

EPA Registration No.  
66171-7  
Vol. 5

# Material Sent for Data Extraction

Reg # 66171-7

Description: \_\_\_\_\_

☒ Material(s) Sent to Data Extraction Contractors

☐ New Stamped Label Dated \_\_\_\_\_

☒ Notification Dated Aug. 14, 2014

☐ New CSF(s) Dated \_\_\_\_\_

☐ Other: \_\_\_\_\_

☒ Decision #: 493517.

☐ Other Action/Comments: \_\_\_\_\_

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: E. Oiguenb...

Phone: 347-0199 Division: AE

Date: \_\_\_\_\_

Created February 3, 2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

Gary E. Gaumer  
Preserve International  
P.O. Box 17003  
Reno, NV 89511

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

AUG 14 2014

SUBJECT: Synergize  
EPA Registration Number: 66171-7  
Application Date: June 02, 2014  
Receipt Date: July 25, 2014

Dear Mr. Gaumer:

This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

- Notification to bring the Synergize label into compliance with Dr. Stephen Bradbury's April 1, 2013 fogging letter.

Based on a review of the submitted information, this notification is acceptable. Your proposed change will be made part of the record for this file.

**General Comments**

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0109 or Velma Noble at (703) 308-6233.

Sincerely,

A handwritten signature in black ink, appearing to read "Velma Noble", is written over a horizontal line.

Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

## DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO<sub>3</sub>) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

## DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

## USE DIRECTIONS:

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to pre-cleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

**BOOT/SHOE WASH:** To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution must be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

**VEHICLES:** To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

## DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARN, RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.

Manufactured by:



PO Box 17003, Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com

Page 1 of 2

# SYNERGIZE™ CLEANER-DISINFECTANT

STAPHYLOCIDAL • PSEUDOMONACIDAL  
• SALMONELLACIDAL • VIRUCIDAL\*  
• PARVOCIDAL • FUNGICIDAL  
ASPERGILLOCIDAL

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, Veterinary Practice, Animal Care, and Animal Laboratory.

## Active Ingredients:

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride.....	26.00%
Glutaraldehyde.....	7.00%
Inert Ingredients.....	67.00%
TOTAL.....	100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes.
- 6) Ventilate building coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

EPA Reg. No.  
EPA Est.

Patent Number:

Batch No:

Net Contents:

66171-7

66171-TN-001, 66171-CA-001

(First letter of batch number indicates establishment)

5,891,922

## NOTIFICATION

Date Reviewed: 08/14/2014  
Reviewed By: E. O. G. G. G.

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

### PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. (For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. This procedure two more times.

**General:** Consult Federal, State or local disposal authorities for approved procedures.

## PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

### DANGER

**KEEP OUT OF REACH OF CHILDREN.** Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS:** This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## FIRST AID

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

**HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

# SYNERGIZE

## HATCHERY ROOMS, INCUBATORS AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING:

When mixing the use solution and pouring it into the fogging apparatus.

**A) HATCHERY ROOMS:** Vacate all personnel from hatchery room to be fogged. Close room off so fog is confined to the hatchery room to be treated. Prepare a stock solution of one (1) part Synergize to forty-two (42) parts water (3 fluid ounces Synergize to 125 fluid ounces water). Fog this solution at a rate of 3.8 ounces per 10,000 cubic feet for the fogging times specified in the chart below. Contact your Preserve International representative to determine the recommended fogging schedule. Do not allow people to breathe or contact the fog. When fogging Synergize, re-entry intervals (REI) and personnel protection equipment (PPE) are determined by the following hatchery room air exchange rates:

ACH for Hatchery Rooms / Incubators and Hatchers	Fogging Time	Re-entry Intervals (REI)	PPE Required
8 Air Exchanges Per Hour	5 Minutes	25 Minutes	No PPE Required
12 Air Exchanges Per Hour	7.5 Minutes	15 Minutes	No PPE Required
16 Air Exchanges Per Hour	10 Minutes	10 Minutes	No PPE Required
20 Air Exchanges Per Hour	12.5 Minutes	10 Minutes	No PPE Required
24 Air Exchanges Per Hour	15 Minutes	10 Minutes	No PPE Required

Under no circumstances must the hatchery room be entered by unprotected persons before the listed re-entry intervals. If the hatchery room must be entered, before the listed re-entry intervals, then the individuals entering the room must wear a long sleeve shirt and pants and an approved NIOSH/MSHA full facepiece respirator, such as the 3M 6700-6900 series, with an organic vapor cartridge, such as the 3M 6001, and a particulate filter, such as the 3M 5N11 & 3M 501 filter retainer.

### B) INCUBATORS AND HATCHERS:

Only for treatment of setters and hatchers after poultry/chicks/eggs have been removed. Not for treatment of hatchers which contain chicks/eggs. Prepare a stock solution of one (1) part Synergize to forty-two (42) parts water (3 fluid ounces Synergize to 125 fluid ounces water) solution at a rate of 3.8 ounces per 10,000 cubic feet for the fogging times specified in the chart above, into setters and hatchers immediately after transfer. Repeat daily. Discontinue hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to breathe this fog and do not enter machines until the fog has been exhausted. To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 of Synergize. If this is done, fog for 30 - 90 seconds once per hour or once every two hours.

### C) POULTRY HOUSES AND LIVESTOCK BUILDINGS:

After the house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, ratite facilities, calf pens and vehicles", double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as possible. Prepare a stock solution of one (1) part Synergize to four (4) parts water (25 fluid ounces Synergize to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, for 125 fluid ounces for each 1000 cubic yards. The fogger itself is placed just inside the door of the building to be treated, or the nozzle of the fogger is inserted through a suitable opening in the door or building. The opening must be large enough to accommodate the nozzle. After fogging, the building must be kept closed for twenty-four (24) hours. After twenty-four (24) hours, the fog must have settled and the house can now be opened and aired. The house must be opened for a minimum of twenty-four (24) hours before it is repopulated with poultry or livestock.

**NOTE FOR POULTRY HOUSES AND LIVESTOCK BUILDINGS:** The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances must a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they must be washed with detergent and water before use for poultry or livestock.

### AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:

This product is used in industrial air washers and air washer systems which have mist-eliminating components.

SYNERGIZE must be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as a basin area. Addition is made intermittently (Slug Dose) or continuously. Badly fouled systems are shock treated with SYNERGIZE. Under these conditions, blowdown must be discontinued for up to 24 hours.

SYNERGIZE is used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

#### Intermittent (Slug Dose) Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

#### Continuous Feed Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** Maintain this treatment level by starting a continuous feed of 1 to 4 ounces per 100 gallons of water. Badly fouled systems must be cleaned before treatment is begun.

**VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/ANIMAL LABORATORY/ANIMAL LIFE SCIENCE LABORATORY/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOOS/PET SHOP/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREEDING FACILITIES/BREEDING AND GROOMING ESTABLISHMENT/TACK SHOPS DISINFECTION DIRECTIONS:** For cleaning and disinfecting the following hard, non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, stalls and catteries. Remove all animals (and) feeds from areas to be treated, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. At 1/2 ounce per gallon of water, in the presence of 1000 ppm of hardness and 5% organic load for a 10-minute contact time, Synergize was found to be effective against Canine Parvovirus.

Staphylococcus aureus A.T.C.C. 6538  
Pseudomonas aeruginosa A.T.C.C. 15442  
Salmonella enterica A.T.C.C. 10708  
Aspergillus fumigatus A.T.C.C. 36607  
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)\*  
Salmonella Enteritidis

Avian Influenza (H3N2)\*  
Escherichia Coli F18  
Porcine circovirus Type 2\*  
Canine parvovirus A.T.C.C. VG-2016  
Salmonella Choleraesuis\*

Manufactured by:

**PRESERVE**  
INTERNATIONAL

Reno, NV 89511 • (800) 995-1607 • [www.preserveinternational.com](http://www.preserveinternational.com)

Page 2 of 2

**DOT SHIPPING NAME**

UN3264, Corrosive Liquid, Acidic, Inorganic,  
n.o.s. (Phosphoric Acid), 8, PG III

5/29/2014



✓ **World Headquarters** P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607  
**Tennessee Operation** 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446  
**California Operation** 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

June 2, 2014

Ms. Velma Noble  
Office of Pesticides Programs (7504C)  
United States Environmental Protection Agency (NOTIFICATION)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Re: Synergize, EPA Registration Number 66171-7

Dear Ms. Noble,

Preserve International hereby submits this notification for our product Synergize, EPA registration number 66171-7. This notification brings Synergize's label into compliance with Dr. Bradbury's April 1, 2013 fogging letter.

Preserve International has removed any claims that the product can be used as an adjunct to sanitization or disinfection.

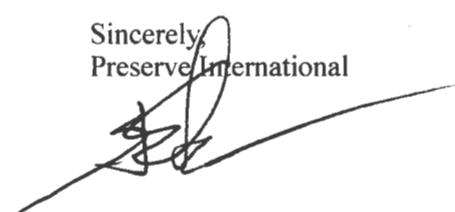
For your review, we have highlighted the area where the adjunct directions were located.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,  
Preserve International

  
Gary E. Gaumer  
President



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 66171-7	2. EPA Product Manager Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SYNERGIZE	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Preserve International PO Box 17003 Reno, NV 89511  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification to bring the Synergize label into compliance with Dr. Stephen Bradbury's April 1, 2013 fogging letter.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 275,250,55,30,4x1,2.5x2		5. Location of Label Directions 	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
Name Gary E. Gaumer		Title President		
		Telephone No. (Include Area Code) 775-853-9776		
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)	
2. Signature 		3. Title President		
4. Typed Name Gary E. Gaumer		5. Date June 2, 2014		



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL  
SAFETY AND POLLUTION  
PREVENTION

June 13, 2014

I, Velma Noble, Regulatory Management Branch 1, Antimicrobials Division, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., Hongkong) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

Preserve International  
P. O. Box 17003  
Reno, NV 89511

EPA Registration Number: 66171-7  
Name of Product: SYNERGIZE

Velma Noble  
Risk Manager 31  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)







✓ **World Headquarters** P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607  
**Tennessee Operation** 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446  
**California Operation** 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

May 27, 2014

Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460-0001

✓ ELMA  
Noble

South Korea

To whom it may concern:

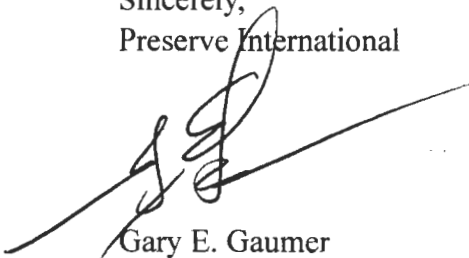
Preserve International submits this package at this time request for for 5 letters of certification (Gold Seal) for our product Synergize, EPA registration number 66171-7.

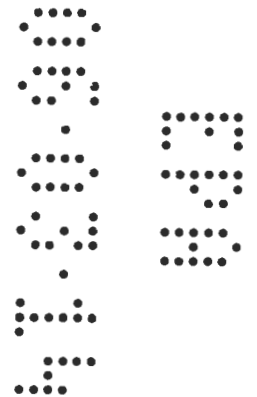
Attached to this cover letter is a receipt reflecting payment for the PRIA fees.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,  
Preserve International

  
Gary E. Gaumer  
President



Receipt for Section 3

S: 953103

Milestone End:

Regulatory Type: Product Registration - Section 3

Re submission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☒ Yes ☐ No

Company: 66171 PRESERVE INTERNATIONAL

Billable: ☒ Yes ☐ No

Risk Manager: Antimicrobials Division, Risk Management Team 31

V

Product #: 66171-7

Product Name: SYNERGIZE

Override#:

Me Too Product Section3:

Me Too Product Name:

Application Date: 27-May-2014

OPP Rec'd Date: 03-Jun-2014

Front End Date: 03-Jun-2014

Risk Manager Send Date: 03-Jun-2014

FFS Due Date: 24-Jul-2014

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description: Gold Seal Certificates (5)

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Other

Gold Seals

View/Edit



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

June 3, 2014

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-491758  
EPA File Symbol or Registration Number: 66171-7  
Product Name: SYNERGIZE  
EPA Receipt Date: 03-Jun-2014  
EPA Company Number: 66171  
Company Name: PRESERVE INTERNATIONAL

GARY GAUMER  
PRESERVE INTERNATIONAL  
PO Box 17003  
RENO, NV 89511-

SUBJECT: Receipt of Request for Gold Seal Certification Letter(s) & Fee Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your request for Gold Seal Certification letter(s) that is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act. We have also received your small business fee waiver request.

The action has been identified as action code M006:

UP TO 5 GOLD SEAL CERTIFICATION LETTERS PER REGISTRATION

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is denied, you will receive an invoice for the outstanding balance. If you have any questions, please contact Betty Williams at (703) 308-0132.

Sincerely,

A handwritten signature in black ink, appearing to be "m/26".

Front End Processing Staff  
Information Technology & Resources Management Division

## Online Payment

## Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

## Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 25FU23UQ

Agency Tracking ID: 74623029211

Transaction Date and Time: 05/27/2014 17:22 EDT

## Payment Summary

## Address Information

Account Holder Gary  
Name: Gaumer

PO Box

Billing Address: 3135

Billing Address 2:

City: Turlock

State / Province: CA

Zip / Postal Code: 95381

Country: USA

## Account Information

American

Card Type: Express

Card Number: \*\*\*\*\*3005

Decision

Number:

Registration  
Number: 66171-7

Preserve

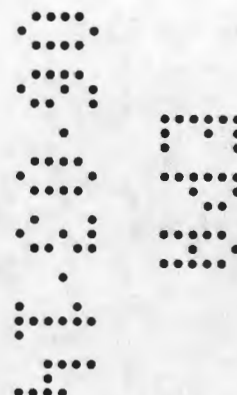
Company Name: International

Company  
Number: 66171

Action Code: M006

## Payment Information

Payment Amount: \$66.00

Transaction Date 05/27/2014  
and Time: 17:22 EDT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

Gary E. Gaumer  
Preserve International  
P.O. Box 17003  
Reno, NV 89511

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

JUN -9 2014

SUBJECT: Synergize  
EPA Registration Number: 66171-7  
Application Date: May 8, 2014  
Receipt Date: May 19, 2014

Dear Mr. Gaumer:

This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

- To update the Formulation Exemption Statement, EPA Form 8570-27

Based on a review of the submitted information, this notification is not acceptable. Your submitted Form 8570-27 contains an additional source of active ingredient. You must provide the CSF with this new source of active ingredient for chemistry review.

**General Comments**

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,

A handwritten signature in black ink, appearing to read "V. Noble", with a long, sweeping horizontal line extending to the right.

Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

**RISK ASSIGNMENT FORM**  
Antimicrobial Division/Regulatory Management Branch I

<b>A</b>	<b>Completed by Product Manager</b>						
<b>PRODUCT REVIEWER:</b> <i>Emilia</i>					<b>RMBI TEAM 31</b>		
<b>Type of Action:</b> <i>Not a Review</i>					<b>EPA File Symbol/Reg No.</b> <i>66171-7</i>		
<b>Decision No.</b>		<b>Submission No.</b>		<b>Fee for Service Action Code:</b>			
<b>FQPA Action Code:</b> <i>332</i>		<b>Non-FQPA Action Code:</b>		<b>PRIA FEE AMOUNT:</b>			
		<small>MONTH</small>	<small>DAY</small>	<small>YEAR</small>			
<b>APPLICATION DATE</b>		<i>5</i>	<i>8</i>	<i>2014</i>			
<b>EPA PIN DATE</b>		<i>5</i>	<i>19</i>	<i>2014</i>			
<b>DATE PM RECEIVED FROM FRONT END</b>		<i>June 18</i>		<i>2014</i>			
<b>DATE SENT TO SCIENCE</b>							
<b>DATE RECEIVED FROM SCIENCE</b>							
<b>DATE DUE TO PM</b>							
<b>Type of Data:</b>	<b>PSB Product Chemistry</b>	<b>PSB Acute Toxicology</b>	<b>PSB Efficacy</b>	<b>RASSB Environmental Fate</b>	<b>RASSB Ecological Effects</b>	<b>RASSB Chronic Toxicology</b>	<b>RASSB Exposure/Residue</b>
<div style="display: flex; justify-content: space-between; padding: 5px;"> <span>ATTACHMENTS: LABELING</span> <span>3-CPFS</span> <span>3-DATA</span> <span>3-OTHERS</span> </div>							
<b>B</b>	<b>For Arctic Slope Contract Only</b>						
	<b>Contract No.: 0052</b>		<b>ARCTIC SLOPE/MANAGER</b>				
	<b>Final Task: Signature</b> _____ <b>(Total hrs)</b> _____						
<b>C</b>	<b>Reviewer Comments:</b>						
<b>DATE FEE PAID:</b>				<b>RESPONSE CODE:</b>		<b>RESPONSE DATE:</b>	



✓ World Headquarters P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607  
Tennessee Operation 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446  
California Operation 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728  
May 8, 2014

Office of Pesticides Programs (7504P)  
United States Environmental Protection Agency (NOTIFICATION)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Re: Synergize, EPA Registration Number 66171-7

To Whom it May Concern:

Preserve International hereby submits this notification to add an additional source for the Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride utilized in Synergize.

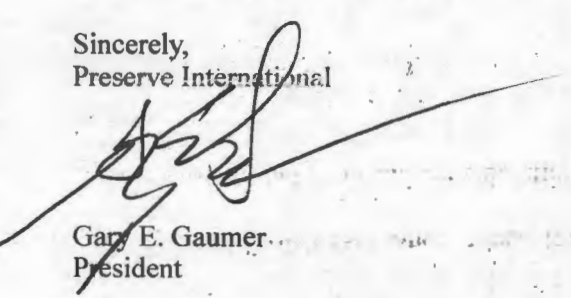
Attached to this cover is an updated Formulators Exemption Statement, EPA Form 8570-27.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,  
Preserve International

  
Gary E. Gaumer  
President



United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address  Preserve International PO Box 17003 Reno, NV 89511	EPA File Symbol/Registration Number 66171-7
	Product Name Synergize
	Date of Confidential Statement of Formula (EPA Form 8570-4) 9/11/2003

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride.

Glutaraldehyde

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

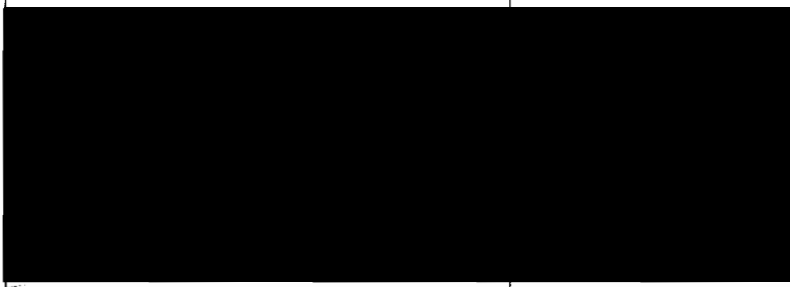
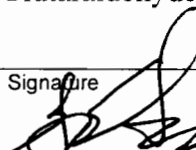
(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☒ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride		
Glutaraldehyde		
Signature 	Name and Title Gary Gaumer, President	Date May 8, 2014

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
Copy 2 - Applicant copy

\*Product ingredient source information may be entitled to confidential treatment\*





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL, SAFETY  
AND POLLUTION PREVENTION

Gary E. Gaumer,  
Preserve International,  
P.O. Box 17003,  
Reno, NV 89511

12 22 2014

Subject: Synergize  
EPA Registration No.: 66171-7  
Notification Date: December 9, 2013  
EPA Receipt Date: December 26, 2013  
Submission #: 945448

Dear Mr. Gaumer,

This letter acknowledges receipt of your notification submitted under the provision of FIFRA section 3(c)9 and PR Notice 98-10.

**Proposed notification request:**

- Addition of PO Box to the company address
- To add a batch lot clarification statement

**General Comments**

Based on a review of the submitted materials your notification for your product, "Synergy", is acceptable.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,

A handwritten signature in black ink, appearing to read "Velma Noble".

Velma Noble  
Product Manager -31  
Regulatory Management Branch  
Antimicrobials Division (7510P)

**RISK ASSIGNMENT FORM**  
Antimicrobial Division/Regulatory Management      nch I

<b>A</b>	<b>Completed by Product Manager</b>						
<b>PRODUCT REVIEWER:</b> <i>Cletis</i>					<b>RMBI</b> <b>TEAM 31</b>		
<b>Type of Action:</b> <i>Not. Finitis</i>					<b>EPA File Symbol/Reg No.</b> <i>66171-7</i>		
<b>Decision No.</b> <i>48 6624</i>			<b>Submission No.</b> <i>945448</i>		<b>Fee for Service Action Code:</b>		
<b>FQPA Action Code:</b> <i>332</i>		<b>Non-FQPA Action Code:</b>			<b>PRIA FEE AMOUNT:</b>		
	<b>MONTH</b>	<b>DAY</b>	<b>YEAR</b>				
<b>APPLICATION DATE</b>	<i>12</i>	<i>9</i>	<b>2014</b>				
<b>EPA PIN DATE</b>	<i>12</i>	<i>26</i>	<b>2014</b>				
<b>DATE PM RECEIVED FROM FRONT END</b>			<b>2014</b>				
<b>DATE SENT TO SCIENCE</b>							
<b>DATE RECEIVED FROM SCIENCE</b>							
<b>DATE DUE TO PM</b>	<i>1</i>	<i>23</i>					
<b>Type of Data:</b>	<b>PSB Product Chemistry</b>	<b>PSB Acute Toxicology</b>	<b>PSB Efficacy</b>	<b>RASSB Environmental Fate</b>	<b>RASSB Ecological Effects</b>	<b>RASSB Chronic Toxicology</b>	<b>RASSB Exposure/Residue</b>
<i>Not. Finitis</i>							
<b>ATTACHMENTS:</b> <b>-LABELING</b> <b>e-CSF(S)</b> <b>e-DATA</b> <b>e-OTHERS</b>							
<b>B</b>	<b>For Arctic Slope Contract Only</b>						
	<b>Contract No.:</b> <i>0052</i>		<b>ARCTIC SLOPE/MANAGER</b>				
	<b>Final Task: Signature</b> _____ <b>(Total hrs)</b> _____						
<b>C</b>	<b>Reviewer Comments:</b>						
<b>DATE FEE PAID:</b>				<b>RESPONSE CODE:</b>		<b>RESPONSE DATE:</b>	

# Receipt for Section 3

S: 945448

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Notification

Company: 66171 PRESERVE INTERNATIONAL



Risk Manager: Antimicrobials Division, Risk Management Team 31

Product #: 66171-7 Product Name: SYNERGIZE

Me Too  
Section3:

Me Too  
Product Name:

Application Date: 09-Dec-2013

OPP Rec'd Date: 26-Dec-2013

Front End Date: 27-Dec-2013

Risk Manager Send Date: 27-Dec-2013

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track:

Not in progress

Receipt Description:

Notification consistent with provisions of PR Notice 98-10

Receipt Content

Paper Label

View/Edit

Form A:

Signature Date:

Form B:

Signature Date:



*World Headquarters* P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607  
*Tennessee Operation* 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446  
*California Operation* 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

December 9, 2013

Office of Pesticides Programs (7504C)  
United States Environmental Protection Agency (NOTIFICATION)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Re: Synergize, EPA Registration number 66171-7

To Whom it May Concern:

Preserve International hereby submits a notification for the following reasons:

- 1) Addition of PO Box 17003 to the address.
- 2) To add a batch (lot) clarification statement: "First letter of batch number indicates establishment."

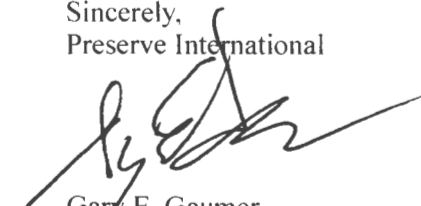
Three copies of the label are attached for your review.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

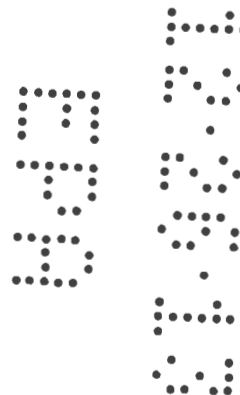
If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,  
Preserve International



Gary E. Gaumer  
President





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 66171-7	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Synergize	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Preserve International PO Box 17003 Reno, NV 89511  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification to add PO Box 17003, and to add a batch (lot) number clarification statement to the currently registered label.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container bulk,275,250,55		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Gary Gaumer		Title President		Telephone No. (Include Area Code) 775-853-9776	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment both under applicable law.					8. Date Application Received (Stamped)  
2. Signature 		3. Title President			
4. Typed Name Gary Gaumer		5. Date December 9, 2013			

## DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO<sub>3</sub>) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

## DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

## USE DIRECTIONS:

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to pre-cleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

**BOOT/SHOE WASH:** To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution must be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

**VEHICLES:** To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

## DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARN, RATITE FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking parlors, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.

Manufactured by:

**PRESERVE**  
INTERNATIONAL  
PO Box 17003, Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com  
Page 1 of 2

# SYNERGIZE™ CLEANER-DISINFECTANT

STAPHYLOCIDAL • PSEUDOMONACIDAL  
• SALMONELLACIDAL • VIRUCIDAL\*  
• PARVOCIDAL • FUNGICIDAL  
ASPERGILLOCIDAL

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, Veterinary Practice, Animal Care, and Animal Laboratory.

## Active Ingredients:

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride.....	26.00%
Glutaraldehyde.....	7.00%
Inert Ingredients.....	67.00%
TOTAL.....	100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

EPA Reg. No.  
EPA Est.

66171-7

66171-TN-001, 66171-CA-001

Patent Number:

5,891,922

Batch No:

Net Contents:

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

## PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container.

## PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. (For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

**General:** Consult Federal, State or local disposal authorities for approved procedures.

## PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

## DANGER

**KEEP OUT OF REACH OF CHILDREN.** Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS:** This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## FIRST AID

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

**HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.



# SYNERGIZE

## HATCHERY ROOMS, INCUBATORS AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING:

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices. Fogging is not used as a sanitizing treatment. Close room off so fog is confined to room to be treated. Hatchery ventilation systems must remain on during fogging. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus.

**A) HATCHERY ROOMS:** Vacate all personnel from hatchery room to be fogged. Close room off so fog is confined to the hatchery room to be treated. Prepare a stock solution of one (1) part Synergize to forty-two (42) parts water (3 fluid ounces Synergize to 125 fluid ounces water). Fog this solution at a rate of 3.8 ounces per 10,000 cubic feet for the fogging times specified in the chart below. Contact your Preserve International representative to determine the recommended fogging schedule. Do not allow people to breathe or contact the fog. When fogging Synergize, re-entry intervals (REI) and personnel protection equipment (PPE) are determined by the following hatchery room air exchange rates:

ACH for Hatchery Rooms / Incubators and Hatchers	Fogging Time	Re-entry Intervals (REI)	PPE Required
8 Air Exchanges Per Hour	5 Minutes	25 Minutes	No PPE Required
12 Air Exchanges Per Hour	7.5 Minutes	15 Minutes	No PPE Required
16 Air Exchanges Per Hour	10 Minutes	10 Minutes	No PPE Required
20 Air Exchanges Per Hour	12.5 Minutes	10 Minutes	No PPE Required
24 Air Exchanges Per Hour	15 Minutes	10 Minutes	No PPE Required

Under no circumstances must the hatchery room be entered by unprotected persons before the listed re-entry intervals. If the hatchery room must be entered, before the listed re-entry intervals, then the individuals entering the room must wear a long sleeve shirt and pants and an approved NIOSH/MSHA full facepiece respirator, such as the 3M 6700-6900 series, with an organic vapor cartridge, such as the 3M 6001, and a particulate filter, such as the 3M 5N11 & 3M 501 filter retainer.

## B) INCUBATORS AND HATCHERS:

Only for treatment of setters and hatchers after poultry/chicks/eggs have been removed. Not for treatment of hatchers which contain chicks/eggs. Prepare a stock solution of one (1) part Synergize to forty-two (42) parts water (3 fluid ounces Synergize to 125 fluid ounces water) solution at a rate of 3.8 ounces per 10,000 cubic feet for the fogging times specified in the chart above, into setters and hatchers immediately after transfer. Repeat daily. Discontinue hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to breathe this fog and do not enter machines until the fog has been exhausted. To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 solution of Synergize. If this is done, fog for 30 - 90 seconds once per hour or once every two hours.

## C) POULTRY HOUSES AND LIVESTOCK BUILDINGS:

After the house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, ratite facilities, calf pens and vehicles", double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as possible. Prepare a stock solution of one (1) part Synergize to four (4) parts water (25 fluid ounces Synergize to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, for 125 fluid ounces for each 1000 cubic yards. The Fogger itself is placed just inside the door of the building to be treated, or the nozzle of the fogger is inserted through a suitable opening in the door or building. The opening must be large enough to accommodate the nozzle. After fogging, the building must be kept closed for twenty-four (24) hours. After twenty-four (24) hours, the fog must have settled and the house can now be opened and aired. The house must be opened for a minimum of twenty-four (24) hours before it is repopulated with poultry or livestock.

**NOTE FOR POULTRY HOUSES AND LIVESTOCK BUILDINGS:** The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances must a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they must be washed with detergent and water before use for poultry or livestock.

## AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:

This product is used in industrial air washers and air washer systems which have mist-eliminating components.

SYNERGIZE must be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as a basin area. Addition is made intermittently (Slug Dose) or continuously. Badly fouled systems are shock treated with SYNERGIZE. Under these conditions, blowdown must be discontinued for up to 24 hours.

SYNERGIZE is used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

## Intermittent (Slug Dose) Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

## Continuous Feed Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** Maintain this treatment level by starting a continuous feed of 1 to 4 ounces per 100 gallons of water. Badly fouled systems must be cleaned before treatment is begun.

**VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/ANIMAL LABORATORY/ANIMAL LIFE SCIENCE LABORATORY/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOOS/PET SHOP/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREEDING FACILITIES/BREEDING AND GROOMING ESTABLISHMENT/TACK SHOPS DISINFECTION DIRECTIONS:** For cleaning and disinfecting the following hard, non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, stalls and catteries. Remove all animals (and) feeds from areas to be treated, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. At 1/2 ounce per gallon of water, in the presence of 1000 ppm of hardness and 5% organic load for a 10-minute contact time, Synergize was found to be effective against Canine Parvovirus.

Staphylococcus aureus A.T.C.C. 6538  
Pseudomonas aeruginosa A.T.C.C. 15442  
Salmonella enterica A.T.C.C. 10708  
Aspergillus fumigatus A.T.C.C. 36007  
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)\*  
Salmonella Enteritidis

Avian Influenza (H3N2)\*  
Escherichia Coli F18  
Porcine circovirus Type 2\*  
Canine parvovirus A.T.C.C. VR-2016\*  
Salmonella Choleraesuis



## DOT SHIPPING NAME

UN3264, Corrosive Liquid, Acidic, Inorganic,  
n.o.s. (Phosphoric Acid), 8, PG III

12/9/13

## DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO<sub>3</sub>) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

## DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm, Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

## USE DIRECTIONS:

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to pre-cleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

**BOOT/SHOE WASH:** To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution must be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

**VEHICLES:** To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

## DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNs, RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking parlors, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.



PO Box 17003, Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com

Page 1 of 2

# SYNERGIZE™ CLEANER-DISINFECTANT

STAPHYLOCIDAL • PSEUDOMONACIDAL  
• SALMONELLACIDAL • VIRUCIDAL\*  
• PARVOCIDAL • FUNGICIDAL  
ASPERGILLOCIDAL

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, Veterinary Practice, Animal Care, and Animal Laboratory.

## Active Ingredients:

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride.....	26.00%
Glutaraldehyde.....	7.00%
Inert Ingredients.....	67.00%
TOTAL.....	100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

### SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

EPA Reg. No.

EPA Est.

Patent Number:

66171-7

66171-TN-001, 66171-CA-001  
(First letter of batch number indicates establishment)

5,891,922

Batch No: \_\_\_\_\_

Net Contents: \_\_\_\_\_

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

### PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container.

### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. (For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. This procedure two more times.

**General:** Consult Federal, State or local disposal authorities for approved procedures.

## PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

### DANGER

**KEEP OUT OF REACH OF CHILDREN.** Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS:** This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## FIRST AID

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

**HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.



## DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO<sub>3</sub>) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

## DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

## USE DIRECTIONS:

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to pre-cleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

**BOOT/SOUE WASH:** To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution must be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

**VEHICLES:** To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

## DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARN, RATITE FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.

Manufactured by:



PO Box 17003, Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com

Page 1 of 2

# SYNERGIZE™ CLEANER-DISINFECTANT

STAPHYLOCIDAL • PSEUDOMONACIDAL  
• SALMONELLACIDAL • VIRUCIDAL\*  
• PARVOCIDAL • FUNGICIDAL  
ASPERGILLOCIDAL

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, Veterinary Practice, Animal Care, and Animal Laboratory.

## Active Ingredients:

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride.....	26.00%
Glutaraldehyde.....	7.00%
Inert Ingredients.....	67.00%
TOTAL.....	100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

### SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

EPA Reg. No.

EPA Est.

Patent Number:

66171-7

66171-TN-001, 66171-CA-001

(First letter of batch number indicates establishment)

5,891,922

Batch No: \_\_\_\_\_

Net Contents: \_\_\_\_\_

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

### PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container.

### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. (For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

**General:** Consult Federal, State or local disposal authorities for approved alternate procedures.

## PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

### DANGER

**KEEP OUT OF REACH OF CHILDREN.** Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS:** This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## FIRST AID

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

**HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

# SYNERGIZE

## HATCHERY ROOMS, INCUBATORS AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING:

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices. Fogging is not used as a sanitizing treatment. Close room off so fog is confined to room to be treated. Hatchery ventilation systems must remain on during fogging. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus.

**A) HATCHERY ROOMS:** Vacate all personnel from hatchery room to be fogged. Close room off so fog is confined to the hatchery room to be treated. Prepare a stock solution of one (1) part Synergize to forty-two (42) parts water (3 fluid ounces Synergize to 125 fluid ounces water). Fog this solution at a rate of 3.8 ounces per 10,000 cubic feet for the fogging times specified in the chart below. Contact your Preserve International representative to determine the recommended fogging schedule. Do not allow people to breathe or contact the fog. When fogging Synergize, re-entry intervals (REI) and personnel protection equipment (PPE) are determined by the following hatchery room air exchange rates:

ACH for Hatchery Rooms / Incubators and Hatchers	Fogging Time	Re-entry Intervals (REI)	PPE Required
8 Air Exchanges Per Hour	5 Minutes	25 Minutes	No PPE Required
12 Air Exchanges Per Hour	7.5 Minutes	15 Minutes	No PPE Required
16 Air Exchanges Per Hour	10 Minutes	10 Minutes	No PPE Required
20 Air Exchanges Per Hour	12.5 Minutes	10 Minutes	No PPE Required
24 Air Exchanges Per Hour	15 Minutes	10 Minutes	No PPE Required

Under no circumstances must the hatchery room be entered by unprotected persons before the listed re-entry intervals. If the hatchery room must be entered, before the listed re-entry intervals, then the individuals entering the room must wear a long sleeve shirt and pants and an approved NIOSH/MSHA full facepiece respirator, such as the 3M 6700-6900 series, with an organic vapor cartridge, such as the 3M 6001, and a particulate filter, such as the 3M 5N11 & 3M 501 filter retainer.

## B) INCUBATORS AND HATCHERS:

Only for treatment of setters and hatchers after poultry/chicks/eggs have been removed. Not for treatment of hatchers which contain chicks/eggs. Prepare a stock solution of one (1) part Synergize to forty-two (42) parts water (3 fluid ounces Synergize to 125 fluid ounces water). solution at a rate of 3.8 ounces per 10,000 cubic feet for the fogging times specified in the chart above, into setters and hatchers immediately after transfer. Repeat daily. Discontinue hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to breathe this fog and do not enter machines until the fog has been exhausted. To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 solution of Synergize. If this is done, fog for 30 - 90 seconds once per hour or once every two hours.

## C) POULTRY HOUSES AND LIVESTOCK BUILDINGS:

After the house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, ratite facilities, calf pens and vehicles", double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as possible. Prepare a stock solution of one (1) part Synergize to four (4) parts water (25 fluid ounces Synergize to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, for 125 fluid ounces for each 1000 cubic yards. The fogger itself is placed just inside the door of the building to be treated, or the nozzle of the fogger is inserted through a suitable opening in the door or building. The opening must be large enough to accommodate the nozzle. After fogging, the building must be kept closed for twenty-four (24) hours. After twenty-four (24) hours, the fog must have settled and the house can now be opened and aired. The house must be opened for a minimum of twenty-four (24) hours before it is repopulated with poultry or livestock.

**NOTE FOR POULTRY HOUSES AND LIVESTOCK BUILDINGS:** The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances must a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they must be washed with detergent and water before use for poultry or livestock.

## AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:

This product is used in industrial air washers and air washer systems which have mist-eliminating components.

SYNERGIZE must be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as a basin area. Addition is made intermittently (Slug Dose) or continuously. Badly fouled systems are shock treated with SYNERGIZE. Under these conditions, blowdown must be discontinued for up to 24 hours.

SYNERGIZE is used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

## Intermittent (Slug Dose) Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

## Continuous Feed Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** Maintain this treatment level by starting a continuous feed of 1 to 4 ounces per 100 gallons of water. Badly fouled systems must be cleaned before treatment is begun.

**VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/ANIMAL LABORATORY/ANIMAL LIFE SCIENCE LABORATORY/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOOS/PET SHOP/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREEDING FACILITIES/BREEDING AND GROOMING ESTABLISHMENT/TACK SHOPS DISINFECTION DIRECTIONS:** For cleaning and disinfecting the following hard, non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, stalls and catteries. Remove all animals (and feeds from areas to be treated, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. At 1/2 ounce per gallon of water, in the presence of 1000 ppm of hardness and 5% organic load for a 10-minute contact time, Synergize was found to be effective against Canine Parvovirus.

Staphylococcus aureus A.T.C.C. 6538  
Pseudomonas aeruginosa A.T.C.C. 15442  
Salmonella enterica A.T.C.C. 10708  
Aspergillus fumigatus A.T.C.C. 3600  
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)\*  
Salmonella Enteritidis

Avian Influenza (H3N2)\*  
Escherichia Coli F18  
Porcine circovirus Type 2\*  
Canine parvovirus A.T.C.C. VR-2016\*  
Salmonella Choleraesuis

Manufactured by:

**PRESERVE**  
INTERNATIONAL

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Page 2 of 2

## DOT SHIPPING NAME

UN3264, Corrosive Liquid, Acidic, Inorganic,  
n.o.s. (Phosphoric Acid), 8, PG III

12/9/13

# SYNERGIZE

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Under no circumstances must the hatchery room be entered by unprotected persons before the listed re-entry intervals. If the hatchery room must be entered, before the listed re-entry intervals, then the individuals entering the room must wear a long sleeve shirt and pants and an approved NIOSH/MSHA full facepiece respirator, such as the 3M 6700-6900 series, with an organic vapor cartridge, such as the 3M 6001, and a particulate filter, such as the 3M 5N11 & 3M 501 filter retainer.

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**NOTE FOR POULTRY HOUSES AND LIVESTOCK BUILDINGS:** The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances must a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they must be washed with detergent and water before use for poultry or livestock.

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This product is used in industrial air washers and air washer systems which have mist-eliminating components.

SYNERGIZE must be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as a basin area. Addition is made intermittently (Slug Dose) or continuously. Badly fouled systems are shock treated with SYNERGIZE. Under these conditions, blowdown must be discontinued for up to 24 hours.

SYNERGIZE is used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

### Intermittent (Slug Dose) Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

### Continuous Feed Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** Maintain this treatment level by starting a continuous feed of 1 to 4 ounces per 100 gallons of water. Badly fouled systems must be cleaned before treatment is begun.

**VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/ANIMAL LABORATORY/ANIMAL LIFE SCIENCE LABORATORY/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOOS/PET SHOP/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREEDING FACILITIES/BREEDING AND GROOMING ESTABLISHMENT/TACK SHOPS DISINFECTION DIRECTIONS:** For cleaning and disinfecting the following hard, non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, stalls and catteries. Remove all animals and people from areas to be treated, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. At 1/2 ounce per gallon of water, in the presence of 1000 ppm of hardness and 5% organic load for a 10-minute contact time, Synergize was found to be effective against Canine Parvovirus.

Staphylococcus aureus A.T.C.C. 6538  
Pseudomonas aeruginosa A.T.C.C. 15442  
Salmonella enterica A.T.C.C. 10708  
Aspergillus fumigatus A.T.C.C. 3680  
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)\*  
Salmonella Enteritidis

Avian Influenza (H3N2)\*  
Escherichia Coli F18  
Porcine circovirus Type 2\*  
Canine parvovirus A.T.C.C. VR-2016\*  
Salmonella Choleraesuis

Manufactured By:

**PRESERVE**  
INTERNATIONAL  
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Page 2 of 2

## DOT SHIPPING NAME

UN3264, Corrosive Liquid, Acidic, Inorganic,  
n.o.s. (Phosphoric Acid), 8, PG III

12/9/13

# Material Sent for Data Extraction

Reg # 66171-7

Description: \_\_\_\_\_

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated \_\_\_\_\_

☐ Notification Dated \_\_\_\_\_

☐ New CSF(s) Dated \_\_\_\_\_

☐ Other: \_\_\_\_\_

☒ Decision #: 479830

☐ Other Action/Comments: \_\_\_\_\_

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: E. O'quendon

Phone: 347-0199 Division: AD

Date: \_\_\_\_\_

Created February 3, 2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

Gary E. Gaumer  
Preserve International  
P.O. Box 17003  
Reno NV 89511

AUG 15 2013

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

SUBJECT: Synergize  
EPA Registration Number: 66171-7  
Application Dated: June 13, 2013  
Receipt Dated: June 14, 2013

Dear Ms. Holcombe:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable.

**Proposed Amendment:**

- To revise the fogging directions for hatchery rooms, incubators and hutches, poultry houses and livestock buildings.


**General Comments**

Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and it's implementing regulation at 40 CFR 152.3.

Should you have any questions or comments concerning this letter, please contact Emilia Oiguenblik at (703) 308-0199 or Velma Noble at (703) 308-6233.

Sincerely,

  
Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510P)

Attachment: Science Review		CONCURRENCES	
SYMBOL			
SURNAME			
DATE			

#### DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleanser. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO<sub>3</sub>) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

#### DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Laver, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

#### USE DIRECTIONS:

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator doors, telephone booths and garbage cans in non-animal areas associated with the noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to pre-cleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

**BOOT/SHOE WASH:** To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution must be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

**VEHICLES:** To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

#### DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.

Sanitize buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARN, RATITE FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.

Manufactured by:

**PRESERVE**  
INTERNATIONAL

Reno, NV 89511 • (800) 995-1607 • [www.preserveinternational.com](http://www.preserveinternational.com)

Page 1 of 2

# SYNERGIZE™ CLEANER-DISINFECTANT

STAPHYLOCIDAL • PSEUDOMONACIDAL

• SALMONELLACIDAL • VIRUCIDAL\*

• PARVOCIDAL • FUNGICIDAL

ASPERGILLOCIDAL



Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Laver, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, Veterinary Practice, Animal Care, and Animal Laboratory.

#### Active Ingredients:

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride.....	26.00%
Glutaraldehyde.....	7.00%
Inert Ingredients.....	67.00%
TOTAL.....	100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.

8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.

9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

EPA Reg. No.

EPA Est.

Patent Number:

66171-7

66171-TN-001, 66171-CA-001

5,891,922

Batch No:

ACCEPTED  
Net Contents:

15 2013

Under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act, this product is hereby registered for use as a disinfectant and cleaner.  
EPA Reg. No. 66171-7

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

#### PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

#### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

**General:** Consult Federal, State or local disposal authorities for approved alternative procedures.

## PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

#### DANGER

**KEEP OUT OF REACH OF CHILDREN.** Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/fining respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS:** This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## FIRST AID

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

**HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

8/13/2013



# SYNERGIZE

## HATCHERY ROOMS, INCUBATORS AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING:

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices. Fogging is not used as a sanitizing treatment. Close room off so fog is confined to room to be treated. Hatchery ventilation systems must remain on during fogging. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus.

**A) HATCHERY ROOMS:** Vacate all personnel from hatchery room to be fogged. Close room off so fog is confined to the hatchery room to be treated. Prepare a stock solution of one (1) part Synergize to forty-two (42) parts water (3 fluid ounces Synergize to 125 fluid ounces water). Fog this solution at a rate of 3.8 ounces per 10,000 cubic feet for the fogging times specified in the chart below. Contact your Preserve International representative to determine the recommended fogging schedule. Do not allow people to breathe or contact the fog. When fogging Synergize, re-entry intervals (REI) and personnel protection equipment (PPE) are determined by the following hatchery room air exchange rates:

ACH for Hatchery Rooms / Incubators and Hatchers	Fogging Time	Re-entry Intervals (REI)	PPE Required
8 Air Exchanges Per Hour	5 Minutes	25 Minutes	No PPE Required
12 Air Exchanges Per Hour	7.5 Minutes	15 Minutes	No PPE Required
16 Air Exchanges Per Hour	10 Minutes	10 Minutes	No PPE Required
20 Air Exchanges Per Hour	12.5 Minutes	10 Minutes	No PPE Required
24 Air Exchanges Per Hour	15 Minutes	10 Minutes	No PPE Required

Under no circumstances must the hatchery room be entered by unprotected persons before the listed re-entry intervals. If the hatchery room must be entered, before the listed re-entry intervals, then the individuals entering the room must wear a long sleeve shirt and pants and an approved SH/MSHA full facepiece respirator, such as the 3M 6700-6900 series, with an organic vapor cartridge, such as the 3M 6001, and a particulate filter, such as the 3M 5N11 & 3M 501 filter retainer.

## INCUBATORS AND HATCHERS:

For treatment of setters and hatchers after poultry/chicks/eggs have been removed. Not for treatment of hatchers which contain chicks/eggs. Prepare a stock solution of one (1) part Synergize to forty-two (42) parts water (3 fluid ounces Synergize to 125 fluid ounces water). Fog this solution at a rate of 3.8 ounces per 10,000 cubic feet for the fogging times specified in the chart above, into setters and hatchers immediately after transfer. Repeat daily. Discontinue hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has been exhausted. To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 solution of Synergize. If this is done, fog for 30 - 90 seconds once per hour or once every two hours.

## C) POULTRY HOUSES AND LIVESTOCK BUILDINGS:

After the house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, ratite facilities, calf pens and vehicles", double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as possible. Prepare a stock solution of one (1) part Synergize to four (4) parts water (25 fluid ounces Synergize to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, for 125 fluid ounces for each 1000 cubic yards. The fogger itself is placed just inside the door of the building to be treated, or the nozzle of the fogger is inserted through a suitable opening in the door or building. The opening must be large enough to accommodate the nozzle. After fogging, the building must be kept closed for twenty-four (24) hours. After twenty-four (24) hours, the fog must have settled and the house can now be opened and aired. The house must be opened for a minimum of twenty-four (24) hours before it is repopulated with poultry or livestock.

**NOTE FOR POULTRY HOUSES AND LIVESTOCK BUILDINGS:** The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances must a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they must be washed with detergent and water before use for poultry or livestock.

## AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:

This product is used in industrial air washers and air washer systems which have mist-eliminating components.

SYNERGIZE must be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as a basin area. Addition is made intermittently (Slug Dose) or continuously. Badly fouled systems are shock treated with SYNERGIZE. Under these conditions, blowdown must be discontinued for up to 24 hours.

SYNERGIZE is used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

## Intermittent (Slug Dose) Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

## Continuous Feed Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** Maintain this treatment level by starting a continuous feed of 1 to 4 ounces per 100 gallons of water. Badly fouled systems must be cleaned before treatment is begun.

**VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/ANIMAL LABORATORY/ANIMAL LIFE SCIENCE LABORATORY/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOOS/PET SHOP/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREEDING FACILITIES/BREEDING AND GROOMING ESTABLISHMENT/TACK SHOPS DISINFECTION DIRECTIONS:** For cleaning and disinfecting the following hard, non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, stalls and catteries. Remove all animals (and) feeds from areas to be treated, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. At 1/2 ounce per gallon of water, in the presence of 1000 ppm of hardness and 5% organic load for a 10-minute contact time, Synergize was found to be effective against Canine Parvovirus.

Staphylococcus aureus A.T.C.C. 6538  
Pseudomonas aeruginosa A.T.C.C. 15442  
Salmonella enterica A.T.C.C. 10708  
Aspergillus fumigatus A.T.C.C. 36607  
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)\*  
Salmonella Enteritidis

Avian Influenza (H3N2)\*  
Escherichia Coli F18  
Porcine circovirus Type 2\*  
Canine parvovirus A.T.C.C. VR-2016\*  
Salmonella Choleraesuis

ACCEPTED

AUG 15 2013

Under the Federal Insecticide, Fungicide, and  
Rodenticide Act is amended, for the  
pesticide registered under  
EPA Reg. No. 66171-7

DOT SHIPPING NAME

UN3264, Corrosive Liquid, Acidic, Inorganic,  
n.o.s. (Phosphoric Acid), 8, PG III

8/13/2013

Manufactured by:  
**PRESERVE**  
INTERNATIONAL  
Reno, NV 89511 • (800) 995-1607 • [www.preserveinternational.com](http://www.preserveinternational.com)  
Page 2 of 2

**RISK ASSIGNMENT FORM**  
Antimicrobial Division/Regulatory Management Branch I

<b>A</b>	Completed by Product Manager						
PRODUCT REVIEWER: <i>Emilia</i>						RMBI <u>TEAM 31</u>	
Type of Action: <i>Amendment with data for New-Use</i>						EPA File Symbol/Reg No. <i>66171-7</i>	
Decision No. <i>497830</i>		Submission No. <i>936796</i>		Fee for Service Action Code: <i>A572</i>			
FQPA Action Code:		Non-FQPA Action Code:		PRIA FEE AMOUNT:			
		MONTH	DAY	YEAR			
APPLICATION DATE		<i>6</i>	<i>13</i>	<i>2013</i>			
EPA PIN DATE		<i>6</i>	<i>14</i>	<i>2013</i>			
DATE PM RECEIVED FROM FRONT END				<i>2013</i>			
DATE SENT TO SCIENCE							
DATE RECEIVED FROM SCIENCE							
DATE DUE TO PM							
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure/Residue
<i>Steno-RASSB - Preserve International has submitted an amendment requiring a data review for Risk Assessment for a change in REI, WPP E or use rate. The study is for Air concentrations for Latchery. Tim Dole looked at the study. Technical screen date 9-27-13 MRID # 49153101</i>							
ATTACHMENTS: -LABELING      e-CSF(S)      e-DATA      e-OTHERS							
<b>B</b>	For Arctic Slope Contract Only						
Contract No.: 0052		ARCTIC SLOPE/MANAGER					
Final Task: Signature _____				(Total hrs) _____			
Reviewer Comments:							
FEE PAID:				RESPONSE CODE:		RESPONSE DATE:	





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

Gary E. Gaumer  
Preserve International  
P/O box 17003  
Reno, NV 89511

AUG 13 2013

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Dear Mr. Gaumer:

The Agency has completed its review and assessment of your application pursuant to Section 33(b)(3) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended by the Pesticide Registration Improvement Extension Act of 2012. The Agency has made a pre-decisional determination that your application for EPA Reg. # 66171-7 cannot be approved unless revisions are made to the label. The necessary label changes are:

1. In the Air Washers and Industrial Scrubbing section, Continuous Feed Method, Subsequent Dose, revise to read as follows replacing the first statement with: *"Maintain this treatment level by starting a continuous feed of 1 to 4 ounces per 100 gallons of water..."*
2. Add mandatory language to the Air Washers and Industrial Scrubbing section as follows: "This product is used in industrial air washers...", "... Addition is made intermittently...", "Badly fouled systems are shock treated...", "Synergize is used in industrial process water..."
3. Delete the following incorrect statement from the Veterinary Practice section: "Thoroughly scrub treated feed racks; automatic feeders, waterers and other equipment which dispenses food or water with soap or detergent and rinse with potable water before reuse." This statement is not appropriate as the beginning of this section indicates that the product is not for treatment of equipment used for animal food or water.

Since there is limited time before the PRIA Decision Due Date expires, it is important to discuss any objections you have to these changes immediately and whether you will need to submit additional data for review. If these discussions determine that submitting data will be necessary, the PRIA decision due date may need to be renegotiated to allow sufficient time to address and resolve such differences. If the PRIA Decision Due Date is not renegotiated, and the label issues are not resolved before the PRIA Decision Due Date, the Agency will send a follow-up letter that will represent the Agency's decision to close out the PRIA decision review time. The follow-up letter will provide the following three options for continuing the review of the application:

- (a) Applicant agrees to all of the terms associated with the draft accepted label as revised by the Agency and requests that it be issued as the accepted final Agency-stamped label; or
- (b) Applicant does not agree to one or more of the terms of the draft accepted label as revised by the Agency and requests additional time to resolve the difference(s); or

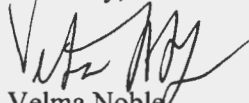
- (c) Applicant withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee.

If the applicant informs EPA that it has concerns as described under (b) above, the applicant will have up to 30 calendar days from the date of that follow-up letter to reach agreement with the Agency on the final version of the label that the Agency will accept. If an agreement cannot be reached within those 30 days, EPA would intend to proceed with denial of the application.

If the applicant agrees to all of the terms of the accepted label as described in (a) above, or if the applicant and EPA resolve any differences as described in (b), the applicant must submit a revised label to EPA. EPA will then provide an accepted final Agency stamped label to the applicant within 2 business days following the applicant's written electronic confirmation of agreement to the Agency including the revised label to be stamped.

If you have any questions, please contact Velma Noble at [noble.velma@epa.gov](mailto:noble.velma@epa.gov) or 703 308 6223.

Sincerely,



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION



July 19, 2013

**MEMORANDUM:**

**Subject:** Occupational Exposure Assessment for the Proposed Label Amendment to Reduce the REI for Synergize Fogging Applications to Hatcheries.

PC Code: 043901, 069175	DP Barcode: D412813
Decision No.: 479830	Registration No.: 66171-7
Petition No.: NA	Regulatory Action: (A572) New Product or Amendment Requiring Data Review for Risk Assessment
Risk Assess Type: Single Chemical	Case No.: NA
TXR No.: NA	CAS No.: 111-30-8, 68391-01-5
MRID No.: 49153101	40 CFR: NA

**From:** Timothy C. Dole, CIH, Industrial Hygienist  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

*Timothy C. Dole*

**Thru:** Timothy Leighton, Senior Scientist  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

*Tim Leighton*

And

Steve Weiss, Branch Chief  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (7510P)

*Steve Weiss*

**To:** Velma Noble, Chemical Review Manager  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Attached is the Occupational Exposure Assessment in support of the proposed label amendment to reduce the re-entry interval (REI) for Synergize fogging applications to hatcheries.

## 1.0 Introduction and Background

Synergize Cleaner-Disinfectant (EPA Reg. No. 66171-7) registered by Preserve International, contains 26.0 percent alkyl dimethyl benzyl ammonium chloride (ADBAC) and 7.0 percent glutaraldehyde (GA) as the active ingredients (a.i.). Preserve International has submitted a proposed label amendment to reduce the Re-entry Interval (REI) for Hatchery Rooms to 10 to 25 minutes. The exact REI, which depends on the ventilation rate expressed as Air Exchanges per Hour (which is the same as Air Changes per Hour) and the fogging time, is listed in a table on page two of the label under the heading: A) Hatchery Rooms. This amendment also includes a rate clarification and reduction whereby 1 part Synergize is added to 42 parts water and fogged into the room at a rate of 3.8 ounces per minute per 10,000 cubic feet. The fogging times are based on the ACH and range from 5 minutes for 8 ACH to 15 minutes for 24 ACH. The fogging is typically accomplished using a fixed system that includes a certain number of nozzles per unit volume to provide good dispersion into the area being treated. The label indicates that the fogging must be done with the ventilation system in operation.

The existing label has an REI of 2 hours for hatchery applications where the application rate is 1 part Synergize to two parts water. This REI was based on the ADBAC Occupational and Residential Exposure (ORE) Assessment (US EPA, 2006a) that was written for the ADBAC RED (US EPA 2006b). The ADBAC ORE assessment calculated an initial concentration of 381 mg/m<sup>3</sup> based on the application of a different product containing 21.7% ADBAC at the rate of 0.42 gallons per 4000 ft<sup>3</sup> to a poultry barn. The poultry barn was assumed to have an ACH of 4 which yielded an 8 hour average air concentration of 44.6 mg/m<sup>3</sup> with no REI and 0.01496 mg/m<sup>3</sup> with a 2 hour REI. These air concentrations yielded MOEs of 0.5 and 1,500 when compared against the NOAEL of 3 mg/kg/day that was used to evaluate ADBAC inhalation exposures. Because the NOAEL was from an oral study, the target MOE was 1,000 and thus the 2 hour REI was required by the RED to achieve an exposure that did not generate risks of concern.

The existing product also contains 7% glutaraldehyde (GA) and calculations that were performed for the GA ORE Assessment (US EPA, 2007a) that was written for the GA RED (US EPA, 2007b) indicated that an REI of 3 hours would be required. The initial concentration of 101 mg/m<sup>3</sup> (25,000 ppb) was calculated based on the application of 1 part product containing 10.725% GA in four parts water at the rate of 125 ounces 1000 yd<sup>3</sup> to a poultry barn. The poultry barn was also assumed to have an ACH of 4. The initial concentration declined to 47 ppb in 94 minutes and 0.30 ppb in 170 minutes. These air concentrations were compared to the ACGIH TLV of 50 ppb, which is relevant for peak exposures, and the EPA short term RfC of 0.32 ppb, which is relevant for 8 hour time weighted average exposures, and based on these comparisons, the REI of 180 minutes (i.e. 3 hours) was included in the RED. The REI was intended to ensure that peak exposures did not exceed the TLV and that 8 hour TWA exposures did not exceed the RfC.

The calculations for ADBAC and GA presented in the RED were based on the poultry house use because it was assumed that it represented worse case conditions since the poultry house is empty and ventilation system is turned off during the application. Preserve International has since indicated these conditions are not representative of hatchery rooms, which are treated while

occupied with eggs, and with the ventilation system in operation. Given this information and the use directions included on the proposed label, the air concentrations during and after fogging applications to a hatchery were calculated and compared to the toxicology endpoints listed in Section 2 of this document.

## 2.0 Toxicology Endpoints

### 2.1 ADBAC

The toxicology endpoints that were used for assessing risk to ADBAC in this memo are the same as those used in the ADBAC ORE Assessment for the RED (US EPA, 2006a) and are included in Table 1. Subsequent to the RED, the OPP guidance is to include the previous 10X uncertainty factor (UF) used for route to route extrapolation as a 10X database uncertainty factor (DBUF) and the target MOE is now 1000.

<b>Table 1 ADBAC Toxicological Endpoints for Inhalation Risk Assessment</b>			
<b>Exposure Scenario</b>	<b>Dose Used in Risk Assessment (mg/kg/day)</b>	<b>Target Margin of Exposure (MOE) or Uncertainty Factor (UF)</b>	<b>Study and Toxicological Effects</b>
Inhalation (Any time point)	NOAEL = 3 mg/kg/day MOE = 100 <sup>A</sup>	UF = 100 (10x inter-species extrapolation, 10x intra-species variation)	Developmental Toxicity – rabbit, MRID 42392801  LOAEL = 9 mg/kg/day, based on clinical signs of toxicity in maternal rabbits
A. An additional 10x is used for route extrapolation to determine if a confirmatory study is needed NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level			

### 2.2 Glutaraldehyde

The toxicological endpoints for GA that were used for this assessment are summarized in Table 2 and they are also the same endpoints that were used in the GA ORE Assessment for the RED (US EPA, 2007a).

<b>Table 2 – Glutaraldehyde Toxicological Endpoints for Inhalation Risk Assessment</b>			
<b>Exposure Scenario</b>	<b>Dose Used in Risk Assessment</b>	<b>UF</b>	<b>Study and Toxicological Effects</b>
<b>Inhalation Exposures</b>			
Short Term Occupational (8 hours/day)	NOAEL = 0.7 mg/m <sup>3</sup> HEC <sub>occ</sub> = 0.041 mg/m <sup>3</sup> 'RfC <sub>occ</sub> ' = 0.0013 mg/m <sup>3</sup> (0.32 ppb*)	30	Two-week inhalation toxicity study in rats and mice (NIH pub 93-3348). LOAEL = 2.0 mg/m <sup>3</sup> based upon histo-pathological alterations of the nasal passages, larynx, trachea and lung.
Intermediate Term Occupational (8 hours/day)	NOAEL = 0.51 mg/m <sup>3</sup> HEC <sub>occ</sub> = 0.03 mg/m <sup>3</sup> 'RfC <sub>occ</sub> ' = 0.001 mg/m <sup>3</sup> (0.24 ppb*)	30	Thirteen week inhalation toxicity study in rats and mice (NIH pub 93-3348). LOAEL = 1.02 mg/m <sup>3</sup> based upon histo-pathological changes of the nasal and respiratory tract epithelium.

<b>Table 2 – Glutaraldehyde Toxicological Endpoints for Inhalation Risk Assessment</b>			
<b>Exposure Scenario</b>	<b>Dose Used in Risk Assessment</b>	<b>UF</b>	<b>Study and Toxicological Effects</b>
Long Term Occupational (8 hours/day)	LOAEL = 0.26 mg/m <sup>3</sup> HEC <sub>occ</sub> = 0.019 mg/m <sup>3</sup> 'RfC <sub>occ</sub> ' = 0.00006 mg/m <sup>3</sup> (0.015 ppb*)	300	Two -Year inhalation toxicity study in rats and mice (MRID 448422-02). LOAEL = 0.26 mg/m <sup>3</sup> based upon squamous epithelial hyperplasia/inflammation and turbinate necrosis.
* Unit Conversion: ppb = (mg/m <sup>3</sup> x 24.45 x 1000 ug/mg) / mw. For glutaraldehyde: 1 ppb = 0.00409 mg/m <sup>3</sup>			

#### Non-EPA Occupational Exposure Limits for Glutaraldehyde

The American Conference of Governmental Hygienists (ACGIH) has evaluated the GA literature and recommended a threshold limit value (TLV) as a ceiling (C) value. A TLV-Ceiling is a threshold limit value that should not be exceeded at any time during the workday and is normally assessed as a 15 minute exposure. Although the ACGIH did review the same animal toxicity studies that were used by EPA, the ACGIH chose a ceiling value because the literature indicated that short term exposures at or below 100 ppb resulted in symptoms of nose, throat, skin and eye irritation among medical workers using GA. The TLV-Ceiling for GA was not based on the same methodology that EPA uses to establish RfCs.

The Occupational Health and Safety Administration (OSHA) has not established a Permissible Exposure Limit (PEL) for GA.

### **3.0 GA and ADBAC Air Concentration Calculations Based on the Proposed Label**

The GA and ADBAC air concentrations were calculated based on the instructions included in the proposed label. These calculations were done for both the increase that occurs during application and the decrease that follows application.

#### **3.1 Increasing Air Concentrations during Application**

To account for the increasing air concentrations during application, a simplified version of the time dependent Well Mixed Box model from Mathematical Models for Estimating Occupational Exposure to Chemicals (AIHA, 2000) was used. This formula is as follows:

$$C_T = G_R/Q * \{1 - e^{[Q*(T-T_0)]/V}\}$$

Where:

- C<sub>T</sub> = Air concentration at time T
- G<sub>R</sub> = Generation rate (mass/time)
- Q = Ventilation rate in cubic feet per minute (CFM)
- T = End time in minutes
- T<sub>0</sub> = Beginning time in minutes
- V = Volume of room in cubic feet

### 3.2 Decreasing Air Concentrations after Application

The decreasing air concentrations after application were calculated using the following single chamber ventilation formula that is included in the EPA Multi-Chamber Concentration and Exposure Model (MCCEM):

$$C_T = C_0 * 0.5 [(T/0.693) * (Q/V)]$$

Where:

$C_T$  = Air concentration at time T  
 $C_0$  = Air Concentration at time zero  
 $Q$  = Ventilation rate in cubic feet per minute (CFM)  
 $T$  = Elapsed time in minutes  
 $V$  = Volume of room in cubic feet

### 3.3 Assumptions

The following assumptions were used in the above formulas:

- The generation rate ( $G_R$ ) for glutaraldehyde (GA) was assumed to be 183.2 mg per minute based on the GA content of the product (7.0 percent), a dilution of 1 part product to 42 parts water and an application rate of 3.8 liquid ounces per minute.
- The generation rate ( $G_R$ ) for ADBAC was assumed to be 680 mg per minute based on the ADBAC content of the product (26.0 percent), a dilution of 1 part product to 42 parts water and an application rate of 3.8 liquid ounces per minute.
- The room volume was assumed to be 10,000 cubic feet based on the label application rate of 3.8 liquid ounces per minute per 10,000 cubic feet.
- The ventilation rate was assumed to be 8, 12, 16, 20 and 24 air changes (or exchanges) per hour based on the label.
- The application (i.e. fogging) times were assumed to be 5, 7.5, 10, 12.5 and 15 minutes, corresponding to the above listed ventilation rates, based on the label.
- The ADBAC daily dose is calculated using a breathing rate is 1.25 M<sup>3</sup> per hour and a body weight of 69 kg, which the average weight for adult females (US EPA, 2011). This body weight was used because the endpoint is based on maternal effects observed during a developmental toxicity study.
- It is assumed that the application is made once per day based on the instructions given for Incubators and Hatchers.

## 4.0 Risk Summary for Inhalation Exposure to ADBAC and GA

### 4.1 Glutaraldehyde (GA)

The estimated air concentrations for GA are summarized in Table 3 and the calculations are included in Appendix A. These air concentrations indicate GA inhalation exposures will not exceed either the ACGIH TLV of 50 ppb for peak exposures upon re-entry into the hatchery, or the EPA RfC of 0.32 ppb as an eight hour time weighted average (8 hr TWA). This means that the risks from inhalation exposure to GA are not of concern.

Table 3 – Glutaraldehyde Estimated Air Concentrations for Hatchery Fogging							
Hatchery Room Ventilation Rate (ACH)	Fogging Time (Minutes)	GA in Air at End of Fogging (ppb)	Re-Entry Interval (Minutes)	GA in Air after REI (ppb)	Exceeds TLV of 50 ppb?	GA 8 Hour TWA Starting after the REI (ppb)	Exceeds EPA RfC of 0.32 ppb?
8	5	578	25	21 ppb	No	0.30	No
12	7.5	615	15	25	No	0.29	No
16	10	552	10	29	No	0.26	No
20	12.5	467	10	12	No	0.088	No
24	15	395	10	4.8	No	0.031	No

ACH = Air Changes per Hour

### 4.1 ADBAC

The estimated air concentrations for ADBAC are summarized in Table 4 and the calculations are included in Appendix B. The MOEs based on these air concentrations range from 4,500 to 45,000 and they are greater than the target MOE of 1,000. This means that the risks from inhalation exposure to ADBAC are not of concern.

Table 4 – ADBAC Estimated Air Concentrations for Hatchery Fogging							
Hatchery Room Ventilation Rate	Fogging Time (Minutes)	ADBAC in Air at End of Fogging (mg/M <sup>3</sup> )	Re-Entry Interval (Minutes)	ADBAC in Air after REI (mg/M <sup>3</sup> )	ADBAC 8 hr TWA <sup>B</sup> (mg/M <sup>3</sup> )	ADBAC Daily Dose <sup>C</sup> (mg/kg/day)	ADBAC MOE <sup>D</sup>
8 ACH <sup>A</sup>	5	8.8	25	0.27	0.0046	0.00066	4,500
12 ACH	7.5	9.3	15	0.38	0.0044	0.00064	4,700
16 ACH	10	8.4	10	0.45	0.0040	0.00058	5,200
20 ACH	12.5	7.2	10	0.18	0.0013	0.00019	16,000
24 ACH	15	6.0	10	0.074	0.00046	0.000067	45,000

A. ACH = Air Changes per Hour

B. 8 hr TWA = Average ADBAC Air concentration for the eight hour period starting after the REI.

C. Daily Dose = [8 hr TWA (mg/m<sup>3</sup>) \* Breathing Rate (1.25 m<sup>3</sup>/hr) \* Exposure Time (8 hr/day)] / [BW (69 kg)]

D. MOE = NOAEL (3 mg/kg/day) / Daily Dose (mg/kg/day)



## **5.0 Conclusions and Recommendations**

The above calculations indicate that proposed label amendments (as indicated on the label of 7/18/2013) to reduce the application rate and the reentry intervals (REIs) will not result in risks of concern for either ADBAC or glutaraldehyde. RASSB recommends that this label be approved as submitted.

## **References**

- AIHA, 2000. Mathematical Models for Estimating Occupational Exposure to Chemicals, AIHA Exposure Assessment Strategies Committee, Modeling Subcommittee, American Industrial Hygiene Association, 2000
- US EPA, 2006a. Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) Occupational and Residential Exposure Assessment for the Antimicrobial Uses, August 1, 2006 (Available on Regulations.Gov under Docket ID EPA-OPP-2006-0339)
- US EPA, 2006b. Registration Eligibility Decision for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC), August, 2006
- US EPA, 2007a. Glutaraldehyde: 2<sup>nd</sup> Revised Occupational and Residential Exposure Assessment for the Registration Eligibility Decision. D327476, September 28, 2007
- US EPA, 2007b. Registration Eligibility Decision for Glutaraldehyde, September 2007.
- US EPA, 2011. Exposure Factors Handbook 2011 Edition (Final). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-09/052F, 2011.

## Appendix A - Glutaraldehyde Air Concentrations for Hatchery Fogging

### Spreadsheet 1 - 24 Air Changes per Hour

#### Application Parameters

Amount Ai in Product	7 percent
Dilution Rate (1 in X)	42
Product Concentration in Diluted Solution	2.33 percent
Application Rate of Dilute Solution	3.8 liquid oz/minute
Application Rate of Product	0.0884 liquid oz/minute
Amount Ai Applied (Assuming 128 liquid oz/ gallon and 8.35 lb/ gallon)	0.000404 lb
Amount Ai Applied (Assuming 454 gm/lb and 1000 mg per gm)	183.2 mg
Volume Treated	10000 ft3
Air Changes per Hour	24
Room Volume (Assuming 28.3 liters/ft3 and 1000 liters/m3)	283 m3
Ventilation Rate	113.2 m3/min

#### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-Qt/V})$$

#### Rate of Decrease Formula

$$C = C@ \text{ Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

Where:

Glutaraldehyde air concentration (C)	mg/m3
Generation Rate (GA)	183.2 mg/min
Ventilation Rate (Q)	113.2 M3/min
Room Volume (V)	283 M3
Elapsed Time (T)	Minutes

Re-Entry Interval (REI) 10 Minutes

#### Increase During Application

Time	GA/Q	QT/V	e <sup>-QT/V</sup>	C (mg/m3)	C (ppb)
0	1.618	0.00	1.000	0.00	0.00
1	1.618	0.40	0.670	0.53	130
2	1.618	0.80	0.449	0.89	218
3	1.618	1.20	0.301	1.13	277
4	1.618	1.60	0.202	1.29	316
5	1.618	2.00	0.135	1.40	342
6	1.618	2.40	0.091	1.47	360
7	1.618	2.80	0.061	1.52	372
8	1.618	3.20	0.041	1.55	380
9	1.618	3.60	0.027	1.57	385
10	1.618	4.00	0.018	1.59	388
11	1.618	4.40	0.012	1.60	391
12	1.618	4.80	0.008	1.61	392
13	1.618	5.20	0.006	1.61	394
14	1.618	5.60	0.004	1.61	394
15	1.618	6.00	0.002	1.61	395

#### Decline following Application

Time (Min)	C (ppb)	8 Hr TWA with REI (ppb)
0	395	
1	265	
2	177	
3	119	
4	80	
5	53	
6	36	
7	24	
8	16	
9	11	
10	7.2	
11	4.8	0.031
12	3.2	
13	2.2	
14	1.5	
15	1.0	

## Appendix A - Glutaraldehyde Air Concentrations for Hatchery Fogging

### Spreadsheet 2 - 20 Air Changes per Hour

#### Application Parameters

Amount Ai in Product	7 percent
Dilution Rate (1 in X)	42
Product Concentration in Diluted Solution	2.33 percent
Application Rate of Dilute Solution	3.8 liquid oz/minute
Application Rate of Product	0.0884 liquid oz/minute
Amount Ai Applied (Assuming 128 liquid oz/ gallon and 8.35 lb/ gallon)	0.000404 lb
Amount Ai Applied (Assuming 454 gm/lb and 1000 mg per gm)	183.2 mg
Volume Treated	10000 ft3
Air Changes per Hour	20
Room Volume (Assuming 28.3 liters/ft3 and 1000 liters/m3)	283 m3
Ventilation Rate	94.3 m3/min

#### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-QT/V})$$

#### Rate of Decrease Formula

$$C = C@ \text{ Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

Where:

Glutaraldehyde air concentration (C)	mg/m3
Generation Rate (GA)	183.2 mg/min
Ventilation Rate (Q)	94.3 M3/min
Room Volume (V)	283 M3
Elapsed Time (T)	Minutes

Re-Entry Interval (REI) 10 Minutes

#### Increase During Application

Time	GA/Q	QT/V	$e^{-QT/V}$	C (mg/m3)	C (ppb)
0	1.942	0.00	1.000	0.00	0.00
1	1.942	0.33	0.717	0.55	135
2	1.942	0.67	0.513	0.94	231
3	1.942	1.00	0.368	1.23	300
4	1.942	1.33	0.264	1.43	350
5	1.942	1.67	0.189	1.58	385
6	1.942	2.00	0.135	1.68	411
7	1.942	2.33	0.097	1.75	429
8	1.942	2.67	0.070	1.81	442
9	1.942	3.00	0.050	1.85	451
10	1.942	3.33	0.036	1.87	458
11	1.942	3.67	0.026	1.89	463
12	1.942	4.00	0.018	1.91	466
12.5	1.942	4.17	0.016	1.91	467

#### Decline following Application

Time (Min)	C (ppb)	8 Hr TWA with REI (ppb)
0	467	
1	335	
2	240	
3	172	
4	123	
5	88	
6	63	
7	45	
8	32	
9	23	
10	17	
11	12	0.088
12	9	
13	6	

## Appendix A - Glutaraldehyde Air Concentrations for Hatchery Fogging

### Spreadsheet 3 - 16 Air Changes per Hour

#### Application Parameters

Amount Ai in Product	7 percent
Dilution Rate (1 in X)	42
Product Concentration in Diluted Solution	2.33 percent
Application Rate of Dilute Solution	3.8 liquid oz/minute
Application Rate of Product	0.0884 liquid oz/minute
Amount Ai Applied (Assuming 128 liquid oz/ gallon and 8.35 lb/ gallon)	0.000404 lb
Amount Ai Applied (Assuming 454 gm/lb and 1000 mg per gm)	183.2 mg
Volume Treated	10000 ft3
Air Changes per Hour	16
Room Volume (Assuming 28.3 liters/ft3 and 1000 liters/m3)	283 m3
Ventilation Rate	75.5 m3/min

#### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-QT/V})$$

#### Rate of Decrease Formula

$$C = C@ \text{ Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

Where:

Glutaraldehyde air concentration (C)	mg/m3
Generation Rate (GA)	183.2 mg/min
Ventilation Rate (Q)	75.5 M3/min
Room Volume (V)	283 M3
Elapsed Time (T)	Minutes

Re-Entry Interval (REI) 10 Minutes

#### Increase During Application

Time	GA/Q	QT/V	$e^{-QT/V}$	C (mg/m3)	C (ppb)
0	2.428	0.00	1.000	0.00	0.00
1	2.428	0.27	0.766	0.57	139
2	2.428	0.53	0.587	1.00	245
3	2.428	0.80	0.449	1.34	327
4	2.428	1.07	0.344	1.59	389
5	2.428	1.33	0.264	1.79	437
6	2.428	1.60	0.202	1.94	474
7	2.428	1.87	0.155	2.05	502
8	2.428	2.13	0.118	2.14	523
9	2.428	2.40	0.091	2.21	540
10	2.428	2.67	0.070	2.26	552

#### Decline following Application

Time (Min)	C (ppb)	8 Hr TWA with REI (ppb)
0	552	
1	423	
2	324	
3	248	
4	190	
5	146	
6	111	
7	85	
8	65	
9	50	
10	38	
11	29	0.261

## Appendix A - Glutaraldehyde Air Concentrations for Hatchery Fogging

### Spreadsheet 4 - 12 Air Changes per Hour

#### Application Parameters

Amount Ai in Product	7 percent
Dilution Rate (1 in X)	42
Product Concentration in Diluted Solution	2.33 percent
Application Rate of Dilute Solution	3.8 liquid oz/minute
Application Rate of Product	0.0884 liquid oz/minute
Amount Ai Applied (Assuming 128 liquid oz/ gallon and 8.35 lb/ gallon)	0.000404 lb
Amount Ai Applied (Assuming 454 gm/lb and 1000 mg per gm)	183.2 mg
Volume Treated	10000 ft3
Air Changes per Hour	12
Room Volume (Assuming 28.3 liters/ft3 and 1000 liters/m3)	283 m3
Ventilation Rate	56.6 m3/min

#### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-Qt/V})$$

#### Rate of Decrease Formula

$$C = C@ \text{ Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

Where:

Glutaraldehyde air concentration (C)	mg/m3
Generation Rate (GA)	183.2 mg/min
Ventilation Rate (Q)	56.6 M3/min
Room Volume (V)	283 M3
Elapsed Time (T)	Minutes

Re-Entry Interval (REI) 15 Minutes

#### Increase During Application

Time	GA/Q	QT/V	e <sup>-QT/V</sup>	C (mg/m3)	C (ppb)
0	3.237	0.00	1.000	0	0
1	3.237	0.20	0.819	0.59	143
2	3.237	0.40	0.670	1.07	261
3	3.237	0.60	0.549	1.46	357
4	3.237	0.80	0.449	1.78	436
5	3.237	1.00	0.368	2.05	500
6	3.237	1.20	0.301	2.26	553
7	3.237	1.40	0.247	2.44	596
7.5	3.237	1.50	0.223	2.51	615

#### Decline following Application

Time (Min)	C (ppb)	8 Hr TWA with REI (ppb)
0	615	
1	503	
2	412	
3	337	
4	276	
5	226	
6	185	
7	152	
8	124	
9	102	
10	83	
11	68	
12	56	
13	46	
14	37	
15	31	
16	25	0.287

## Appendix A - Glutaraldehyde Air Concentrations for Hatchery Fogging

### Spreadsheet 5 - 8 Air Changes per Hour

#### Application Parameters

Amount Ai in Product	7 percent
Dilution Rate (1 in X)	42
Product Concentration in Diluted Solution	2.33 percent
Application Rate of Dilute Solution	3.8 liquid oz/minute
Application Rate of Product	0.0884 liquid oz/minute
Amount Ai Applied (Assuming 128 liquid oz/ gallon and 8.35 lb/ gallon)	0.000404 lb
Amount Ai Applied (Assuming 454 gm/lb and 1000 mg per gm)	183.2 mg
Volume Treated	10000 ft3
Air Changes per Hour	8
Room Volume (Assuming 28.3 liters/ft3 and 1000 liters/m3)	283 m3
Ventilation Rate	37.7 m3/min

#### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-Qt/V})$$

#### Rate of Decrease Formula

$$C = C@ \text{ Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

Where:

Glutaraldehyde air concentration (C)	mg/m3
Generation Rate (GA)	183.2 mg/min
Ventilation Rate (Q)	37.7 M3/min
Room Volume (V)	283 M3
Elapsed Time (T)	Minutes

Re-Entry Interval (REI) 25 Minutes

#### Increase During Application

Time	GA/Q	QT/V	$e^{-QT/V}$	C (mg/m3)	C (ppb)
0	4.855	0.00	1.000	0	0
1	4.855	0.13	0.875	0.61	148
2	4.855	0.27	0.766	1.14	278
3	4.855	0.40	0.670	1.60	391
4	4.855	0.53	0.587	2.01	491
5	4.855	0.67	0.513	2.36	578

#### Decline following Application

Time (Min)	C (ppb)	8 Hr TWA with REI (ppb)
0	578	
1	505	
2	442	
3	387	
4	339	
5	297	
6	259	
7	227	
8	199	
9	174	
10	152	
11	133	
12	117	
13	102	
14	89	
15	78	
16	68	
17	60	
18	52	
19	46	
20	40	
21	35	
22	31	
23	27	
24	24	
25	21	
26	18	0.300

## Appendix B - ADBAC Air Concentrations for Hatchery Fogging Spreadsheet 1 - 24 Air Changes per Hour

### Application Parameters

Amount Ai in Product	26 percent
Dilution Rate (1 in X)	42
Product Concentration in Diluted Solution	2.33 percent
Application Rate of Dilute Solution	3.8 liquid oz/minute
Application Rate of Product	0.0884 liquid oz/minute
Amount Ai Applied (Assuming 128 liquid oz/ gallon and 8.35 lb/ gallon)	0.00150 lb
Amount Ai Applied (Assuming 454 gm/lb and 1000 mg per gm)	680.5 mg
Volume Treated	10000 ft3
Air Changes per Hour	24
Room Volume (Assuming 28.3 liters/ft3 and 1000 liters/m3)	283 m3
Ventilation Rate	113.2 m3/hr

### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-Qt/V})$$

Where:

ADBAC air concentration (C)	mg/m3
Generation Rate (GA)	680.5 mg/min
Ventilation Rate (Q)	113.2 M3/min
Room Volume (V)	283 M3
Elapsed Time (T)	Minutes

### Rate of Decrease Formula

$$C = C@ \text{ Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

Re-entry Interval (REI) = 10 Minutes

### Increase During Application

Time	GA/Q	QT/V	e <sup>-QT/V</sup>	C (mg/m3)
0	6.011	0.00	1.000	0.00
1	6.011	0.40	0.670	1.98
2	6.011	0.80	0.449	3.31
3	6.011	1.20	0.301	4.20
4	6.011	1.60	0.202	4.80
5	6.011	2.00	0.135	5.20
6	6.011	2.40	0.091	5.47
7	6.011	2.80	0.061	5.65
8	6.011	3.20	0.041	5.77
9	6.011	3.60	0.027	5.85
10	6.011	4.00	0.018	5.90
11	6.011	4.40	0.012	5.94
12	6.011	4.80	0.008	5.96
13	6.011	5.20	0.006	5.98
14	6.011	5.60	0.004	5.99
15	6.011	6.00	0.002	6.00

### Decline following Application

Time (Min)	C (mg/m3)	8 Hr TWA with REI (mg/m3)
0	6.0	
1	4.0	
2	2.7	
3	1.8	
4	1.2	
5	0.81	
6	0.54	
7	0.36	
8	0.24	
9	0.16	
10	0.11	
11	0.074	0.00046
12	0.049	
13	0.033	
14	0.022	
15	0.015	



## Appendix B - ADBAC Air Concentrations for Hatchery Fogging Spreadsheet 2 - 20 Air Changes per Hour

### Application Parameters

Amount Ai in Product	26 percent
Dilution Rate (1 in X)	42
Product Concentration in Diluted Solution	2.33 percent
Application Rate of Dilute Solution	3.8 liquid oz/minute
Application Rate of Product	0.0884 liquid oz/minute
Amount Ai Applied (Assuming 128 liquid oz/ gallon and 8.35 lb/ gallon)	0.00150 lb
Amount Ai Applied (Assuming 454 gm/lb and 1000 mg per gm)	680.5 mg
Volume Treated	10000 ft3
Air Changes per Hour	20
Room Volume (Assuming 28.3 liters/ft3 and 1000 liters/m3)	283 m3
Ventilation Rate	94.3 m3/hr

### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-Qt/V})$$

Where:

ADBAC air concentration (C)	mg/m3
Generation Rate (GA)	680.5 mg/min
Ventilation Rate (Q)	94.3 M3/min
Room Volume (V)	283 M3
Elapsed Time (T)	Minutes

### Rate of Decrease Formula

$$C = C@ \text{ Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

Re-entry Interval (REI) = 10 Minutes

### Increase During Application

Time	GA/Q	QT/V	$e^{-QT/V}$	C (mg/m3)
0	7.214	0.00	1.000	0.00
1	7.214	0.33	0.717	2.04
2	7.214	0.67	0.513	3.51
3	7.214	1.00	0.368	4.56
4	7.214	1.33	0.264	5.31
5	7.214	1.67	0.189	5.85
6	7.214	2.00	0.135	6.24
7	7.214	2.33	0.097	6.51
8	7.214	2.67	0.070	6.71
9	7.214	3.00	0.050	6.85
10	7.214	3.33	0.036	6.96
11	7.214	3.67	0.026	7.03
12	7.214	4.00	0.018	7.08
12.5	7.214	4.17	0.016	7.10

### Decline following Application

Time (Min)	C (mg/m3)	8 Hr TWA with REI (mg/m3)
0	7.1	
1	5.1	
2	3.6	
3	2.6	
4	1.9	
5	1.3	
6	1.0	
7	0.69	
8	0.49	
9	0.35	
10	0.25	
11	0.18	0.0013
12	0.13	
13	0.09	

## Appendix B - ADBAC Air Concentrations for Hatchery Fogging Spreadsheet 3 -16 Air Changes per Hour

### Application Parameters

Amount Ai in Product	26 percent
Dilution Rate (1 in X)	42
Product Concentration in Diluted Solution	2.33 percent
Application Rate of Dilute Solution	3.8 liquid oz/minute
Application Rate of Product	0.0884 liquid oz/minute
Amount Ai Applied (Assuming 128 liquid oz/ gallon and 8.35 lb/ gallon)	0.00150 lb
Amount Ai Applied (Assuming 454 gm/lb and 1000 mg per gm)	680.5 mg
Volume Treated	10000 ft3
Air Changes per Hour	16
Room Volume (Assuming 28.3 liters/ft3 and 1000 liters/m3)	283 m3
Ventilation Rate	75.5 m3/hr

### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-Qt/V})$$

Where:

ADBAC air concentration (C)	mg/m3
Generation Rate (GA)	680.5 mg/min
Ventilation Rate (Q)	75.5 M3/min
Room Volume (V)	283 M3
Elapsed Time (T)	Minutes

### Rate of Decrease Formula

$$C = C@ \text{ Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

Re-entry Interval (REI) = 10 Minutes

### Increase During Application

Time	GA/Q	QT/V	$e^{-QT/V}$	C (mg/m3)
0	9.017	0.00	1.000	0.0
1	9.017	0.27	0.766	2.1
2	9.017	0.53	0.587	3.7
3	9.017	0.80	0.449	5.0
4	9.017	1.07	0.344	5.9
5	9.017	1.33	0.264	6.6
6	9.017	1.60	0.202	7.2
7	9.017	1.87	0.155	7.6
8	9.017	2.13	0.118	7.9
9	9.017	2.40	0.091	8.2
10	9.017	2.67	0.070	8.4

### Decline following Application

Time (Min)	C (mg/m3)	8 Hr TWA with REI (mg/m3)
0	8.4	
1	6.4	
2	4.9	
3	3.8	
4	2.9	
5	2.2	
6	1.7	
7	1.3	
8	1.0	
9	0.76	
10	0.58	
11	0.45	0.0040

## Appendix B - ADBAC Air Concentrations for Hatchery Fogging Spreadsheet 4 -12 Air Changes per Hour

### Application Parameters

Amount Ai in Product	26 percent
Dilution Rate (1 in X)	42
Product Concentration in Diluted Solution	2.33 percent
Application Rate of Dilute Solution	3.8 liquid oz/minute
Application Rate of Product	0.0884 liquid oz/minute
Amount Ai Applied (Assuming 128 liquid oz/ gallon and 8.35 lb/ gallon)	0.00150 lb
Amount Ai Applied (Assuming 454 gm/lb and 1000 mg per gm)	680.5 mg
Volume Treated	10000 ft3
Air Changes per Hour	12
Room Volume (Assuming 28.3 liters/ft3 and 1000 liters/m3)	283 m3
Ventilation Rate	56.6 m3/hr

### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-Qt/V})$$

Where:

ADBAC air concentration (C)	mg/m3
Generation Rate (GA)	680.5 mg/min
Ventilation Rate (Q)	56.6 M3/min
Room Volume (V)	283 M3
Elapsed Time (T)	Minutes

### Rate of Decrease Formula

$$C = C@ \text{Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

Re-entry Interval (REI) = 15 Minutes

### Increase During Application

Time	GA/Q	QT/V	$e^{-QT/V}$	C (mg/m3)
0	12.023	0.00	1.000	0
1	12.023	0.20	0.819	2.2
2	12.023	0.40	0.670	4.0
3	12.023	0.60	0.549	5.4
4	12.023	0.80	0.449	6.6
5	12.023	1.00	0.368	7.6
6	12.023	1.20	0.301	8.4
7	12.023	1.40	0.247	9.1
7.5	12.023	1.50	0.223	9.3

### Decline following Application

Time (Min)	C (mg/m3)	8 Hr TWA with REI (mg/m3)
0	9.3	
1	7.6	
2	6.3	
3	5.1	
4	4.2	
5	3.4	
6	2.8	
7	2.3	
8	1.9	
9	1.5	
10	1.3	
11	1.0	
12	0.85	
13	0.69	
14	0.57	
15	0.46	
16	0.38	0.0044

## Appendix B - ADBAC Air Concentrations for Hatchery Fogging

### Spreadsheet 5 - 8 Air Changes per Hour

#### Application Parameters

Amount Ai in Product	26 percent
Dilution Rate (1 in X)	42
Product Concentration in Diluted Solution	2.33 percent
Application Rate of Dilute Solution	3.8 liquid oz/minute
Application Rate of Product	0.0884 liquid oz/minute
Amount Ai Applied (Assuming 128 liquid oz/ gallon and 8.35 lb/ gallon)	0.00150 lb
Amount Ai Applied (Assuming 454 gm/lb and 1000 mg per gm)	680.5 mg
Volume Treated	10000 ft <sup>3</sup>
Air Changes per Hour	8
Room Volume (Assuming 28.3 liters/ft <sup>3</sup> and 1000 liters/m <sup>3</sup> )	283 m <sup>3</sup>
Ventilation Rate	37.7 m <sup>3</sup> /hr

#### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-Qt/V})$$

Where:

ADBAC air concentration (C)	mg/m <sup>3</sup>
Generation Rate (GA)	680.5 mg/min
Ventilation Rate (Q)	37.7 M <sup>3</sup> /min
Room Volume (V)	283 M <sup>3</sup>
Elapsed Time (T)	Minutes

#### Rate of Decrease Formula

$$C = C@ \text{Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

Re-entry Interval (REI) = 25 Minutes

#### Increase During Application

Time	GA/Q	QT/V	e <sup>-QT/V</sup>	C (mg/m <sup>3</sup> )
0	18.034	0.00	1.000	0
1	18.034	0.13	0.875	2.25
2	18.034	0.27	0.766	4.22
3	18.034	0.40	0.670	5.94
4	18.034	0.53	0.587	7.45
5	18.034	0.67	0.513	8.77

#### Decline following Application

Time (Min)	C (mg/m <sup>3</sup> )	8 Hr TWA with REI (mg/m <sup>3</sup> )
0	8.8	
1	7.7	
2	6.7	
3	5.9	
4	5.1	
5	4.5	
6	3.9	
7	3.4	
8	3.0	
9	2.6	
10	2.3	
11	2.0	
12	1.8	
13	1.5	
14	1.4	
15	1.2	
16	1.0	
17	0.91	
18	0.80	
19	0.70	
20	0.61	
21	0.53	
22	0.47	
23	0.41	
24	0.36	
25	0.31	0.0046

# DATA PACKAGE BEAN SHEET

Date: 27-Jun-2013

Page 1 of 1

Decision #: 479830

DP #: (412813)

PRIA

Parent DP #:

Submission #: 936796

E-Sub #:

## \*\*\* Registration Information \*\*\*

Registration: 66171-7 - SYNERGIZE

Company: 66171 - PRESERVE INTERNATIONAL

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Emilia Oiguenblik EOIGUENB

Sent Date: TENTATIVE Due Date: 07-Apr-2014

Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A572) NEW PRODUCT OR AMENDMENT REQUIRING DATA REVIEW FOR RISK ASSESSI

Ingredients: 043901, Glutaraldehyde(7%)

069175, Alkyl\* dimethyl benzyl ammonium chloride \*(67%C12, 25%C14, 7%C16, 1%C18)(26%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 27-Jun-2013

Due Back:

DP Ingredient: 043901, Glutaraldehyde

069175, Alkyl\* dimethyl benzyl ammonium chloride \*(67%C12, 25%C14, 7%C16, 1%C18)

DP Title: Amendment

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #:

### Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 07-Apr-2014

Team Name: RASSB1

Science Due Date:

Reviewer Name:

Sub Data Package Due Date:

Contractor Name:

## \*\*\* Studies Sent for Review \*\*\*

No Studies

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

Steve- RASSB- Preserve International has submitted an amendment requiring a data review for Risk Assessment for a change in REI or PPE on use rate. The study is for air concentrations for latchery.. Tim Dole looked at the study. Technical Screen dated 9-27-13 MRID #49153101


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**Certification with Respect to Citation of Data**

 Applicant's/Registrant's Name, Address, and Telephone Number  
 Preserve International, PO Box 17003, Reno, NV 89511

 EPA Registration Number/File Symbol  
 66171-7

 Active Ingredient(s) and/or representative test compound(s)  
 Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride, Glutaraldehyde

 Date  
 May 25, 2011

 General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)  
 Farm, Indoor non-food, animal, cooling and processed water treatment

 Product Name  
 Synergize

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

 Date  
 6/19/13

 Typed or Printed Name and Title  
 Gary E. Gaumer, President




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DATA MATRIX

Date May 24, 2011		EPA Reg No./File Symbol 66171-7		Page 1 of 3	
Applicant's/Registrant's Name & Address Preserve International, PO Box 17003, Reno, NV 89511		Product Synergize			
Ingredient Alkyl dimethyl benzyl ammonium chloride, Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Submission of Product Chemistry and Efficacy Data	44433700	Preserve International	Own	
	in support of the application for registration of Synergize				
	Disinfectant.				
61-1	Product Identity & Disclosure of Ingredients	44433701	Preserve International	Own	
61-2	Product Identity - Beginning Materials & Mfg. Process	44433701	Preserve International	Own	
61-3	Product Identity - Discussion of Formation of Impurities	44433701	Preserve International	Own	
62-2	Analysis of Ingredients - Certification of Limits	44433701	Preserve International	Own	
63-0	Reports of Multiple Physical/Chemical Characteristics	44433701	Preserve International	Own	
-0-	Selected Physical Characteristics	44433702	Preserve International	Own	
62-1	Analysis of Ingredients-Preliminary Analysis of Product	44433703	Preserve International	Own	
62-3	Analysis of Ingredients-Analytical Method to Verify Limits	44433703	Preserve International	Own	
62-1	Analysis of Ingredients-Preliminary Analysis of Product	44433704	Preserve International	Own	
62-3	Analysis of Ingredients-Analytical Method to Verify Limits	44433704	Preserve International	Own	
	AOAC Disinfectant Testing (Efficacy)	44433705	Preserve International	Own	
	AOAC Disinfectant Testing (Efficacy)-Addendum 1		Preserve International	Own	
Signature 			Name and Title Gary E. Gaumer, President		Date June 19, 2013

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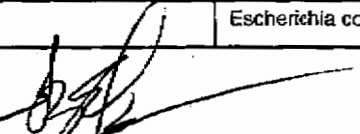


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Date May 24, 2011		EPA Reg No./File Symbol 66171-7		Page 2 of 3	
Applicant's/Registrant's Name & Address Preserve International, PO Box 17003, Reno, NV 89511		Product Synergize			
Ingredient Alkyl dimethyl benzyl ammonium chloride, Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Toxicity Data Submission Cover Sheet	44569500	Preserve International	Own	
81-1	Acute Tox & Irritation - Acute Oral Toxicity	44569501	Preserve International	Own	
81-2	Acute Tox & Irritation - Acute Dermal Toxicity	44569502	Preserve International	Own	
81-5	Acute Tox & Irritation - Primary Dermal Irritation	44569503	Preserve International	Own	
81-4	Acute Tox & Irritation - Primary Eye Irritation	44569504	Preserve International	Own	
81-3	Acute Tox & Irritation - Acute Inhalation Toxicity	44569505	Preserve International	Own	
81-6	Acute Tox & Irritation - Dermal Sensitization	44569506	Preserve International	Own	
	Fungicidal Data Submission Cover Sheet	45147100	Preserve International	Own	
	AOAC Fungicidal Product Test - Efficacy Data	45147101	Preserve International	Own	
	Porcine Respiratory & Reproductive Cover Sheet	46391200	Preserve International	Own	
	Porcine Respiratory & Reproductive Syndrome Virus Data	46391301	Preserve International	Own	
	Avian Influenza A (H3N2) Virus Cover Sheet	46770300	Preserve International	Own	
	Avian Influenza A (H3N2) Virus Data	46770301	Preserve International	Own	
	Escherichia coli (F18) Cover Sheet	46770300	Preserve International	Own	
	Escherichia coli (F18) Data	46770302	Preserve International	Own	
Signature 			Name and Title Gary E. Gaumer, President		Date June 19, 2013

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Page 3 of 3

**Applicant's/Registrant's Name & Address**  
 Serve International, PO Box 17003, Reno, NV 89511

Product Synergize

**Ingredient** Alkyl dimethyl benzyl ammonium chloride, Glutaraldehyde

[illegible]

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Date May 24, 2011		EPA Reg No./File Symbol 66171-7		Page 1 of 3	
Registrant's Name & Address Preserve International, PO Box 17003, Reno, NV 89511		Product Synergize			
Ingredient Alky dimethyl benzyl ammonium chloride, Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Signature 	Name and Title Gary E. Gaumer, President	

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DATA MATRIX

Date May 24, 2011		EPA Reg No./File Symbol 66171-7		Page 2 of 3	
Applicant's/Registrant's Name & Address Preserve International, PO Box 17003, Reno, NV 89511		Product Synergize			
Ingredient Alkyl dimethyl benzyl ammonium chloride, Glutaraldehyde					
Guideline Reference Number	Guideline Study Name	MIRID Number	Submitter	Status	Note
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
Signature 			Name and Title Gary E. Gaumer, President		Date June 19, 2013



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DATA MATRIX

Date May 24, 2011	EPA Reg No./File Symbol 86171-7	Page 3 of 3
licant's/Registrant's Name & Address erve International, PO Box 17003, Reno, NV 89511	Product Synergize	

Ingredient Alkyl dimethyl benzyl ammonium chloride, Gluteraldehyde

Guideline Reference Number	Guideline Study Name	VRID Number	Submitter	Status	Note
			Preserve International	Own	
			Preserve International	Own	
			Preserve International	Own	
Signature 	Name and Title Gary E. Gaumer, President			Date June 19, 2013	

## Oiguenblik, Emilia

---

**From:** Noble, Velma  
**Sent:** Wednesday, August 07, 2013 9:27 AM  
**To:** Gary Gaumer  
**Cc:** Oiguenblik, Emilia  
**Subject:** RE: Synergize

Hi Mr. Gaumer,

Tim has finished his review. Emilia who works on the team is working on this PRIA. I just returned to the office. I will give you an update next week.

-----Original Message-----

**From:** Gary Gaumer [<mailto:gegaumer@preserveinc.com>]  
**Sent:** Tuesday, July 30, 2013 5:20 PM  
**To:** Noble, Velma  
**Cc:** Dole, Timothy  
**Subject:** Synergize

Hello Velma,

I am checking on the progress of the Synergize amendment. I believe Timothy mentioned that he thought it would be wrapped up this week.

Thanks for the help.

GG

**Oiguenblik, Emilia**

---

**From:** Gary E. Gaumer [gegaumer@preserveinc.com]  
**Sent:** Tuesday, August 13, 2013 1:12 PM  
**To:** Oiguenblik, Emilia  
**Cc:** Noble, Velma  
**Subject:** Re: Synergize  
**Attachments:** Synergize Master (Fogging) PENDING 8-13-13.pdf

Hello,

Thank you for the reply.

The attached label should have all the changes you are requesting.

We greatly all the help you are lending in the effort to get this out of the EPA ASAP...

Thank you much...

GG

---

**From:** "Oiguenblik, Emilia" <Oiguenblik.Emilia@epa.gov>  
**Date:** Tuesday, August 13, 2013 9:55 AM  
**To:** Gary Gaumer <gegaumer@preserveinc.com>  
**Cc:** Velma Noble <noble.velma@epa.gov>  
**Subject:** RE: Synergize

Dear Mr. Gaumer,

Please find the attached PDF containing the changes required per letter dated September 22, 2011, fix the label and e-mail it to me.

Thanks,

Emilia

---

**From:** Gary E. Gaumer [mailto:gegaumer@preserveinc.com]  
**Sent:** Monday, August 12, 2013 4:20 PM  
**To:** Oiguenblik, Emilia  
**Subject:** Re: Synergize

Excellent.. Thank you very much.

GG



---

**From:** "Oiguenblik, Emilia" <Oiguenblik.Emilia@epa.gov>  
**Date:** Monday, August 12, 2013 1:06 PM  
**To:** Gary Gaumer <gegaumer@preserveinc.com>  
**Subject:** RE: Synergize

I am working on it now

---

**From:** Gary E. Gaumer [mailto:gegaumer@preserveinc.com]  
**Sent:** Monday, August 12, 2013 3:38 PM  
**To:** Oiguenblik, Emilia  
**Subject:** Re: Synergize

Hello Emilia,

Just checking to see if you have had any luck reviewing our amendment.

Thank you,

GG

---

**From:** "Oiguenblik, Emilia" <Oiguenblik.Emilia@epa.gov>  
**Date:** Thursday, August 8, 2013 11:01 AM  
**To:** Gary Gaumer <gegaumer@preserveinc.com>  
**Subject:** RE: Synergize

At first I will e-mail you the letter with some comments improving the label. After receiving the corrected label (via e-mail too) from you and getting Velma's approval I will send everything attached to e-mail.

Emilia

---

**From:** Gary E. Gaumer [mailto:gegaumer@preserveinc.com]  
**Sent:** Thursday, August 08, 2013 1:53 PM  
**To:** Oiguenblik, Emilia  
**Cc:** Noble, Velma  
**Subject:** Re: Synergize

Thank you. We *eagerly* await your reply.

Can you do me a favor and email me a copy of the letter when you have it put together?

Thank you again,

GG

---

**From:** "Oiguenblik, Emilia" <[Oiguenblik.Emilia@epa.gov](mailto:Oiguenblik.Emilia@epa.gov)>  
**Date:** Thursday, August 8, 2013 10:43 AM  
**To:** Gary Gaumer <[gegaumer@preserveinc.com](mailto:gegaumer@preserveinc.com)>  
**Cc:** Velma Noble <[noble.velma@epa.gov](mailto:noble.velma@epa.gov)>  
**Subject:** RE: Synergize

Thanks for your letter.  
I will let you know about any questions.  
I hope to finish this submission ASAP.

Sincerely,

Emilia

---

**From:** Gary E. Gaumer [<mailto:gegaumer@preserveinc.com>]  
**Sent:** Thursday, August 08, 2013 1:38 PM  
**To:** Oiguenblik, Emilia  
**Subject:** FW: Synergize

Hi Emilia,

I understand from the email below, you are working on the PRIA amendment for our product Synergize, EPA registration number 66171-7.

I am just checking to see if you have any questions I can answer, and to ascertain when you think you will be finished.

Thank you for your time.

Gary Gaumer  
775-853-9776

---

**From:** Velma Noble <[noble.velma@epa.gov](mailto:noble.velma@epa.gov)>  
**Date:** Wednesday, August 7, 2013 6:27 AM  
**To:** Gary Gaumer <[gegaumer@preserveinc.com](mailto:gegaumer@preserveinc.com)>  
**Cc:** "Oiguenblik, Emilia" <[Oiguenblik.Emilia@epa.gov](mailto:Oiguenblik.Emilia@epa.gov)>  
**Subject:** RE: Synergize

Hi Mr. Gaumer,

Tim has finished his review. Emilia who works on the team is working on this PRIA. I just returned to the office. I will give you and update next week.

-----Original Message-----

From: Gary Gaumer [<mailto:gegaumer@preserveinc.com>]

Sent: Tuesday, July 30, 2013 5:20 PM

To: Noble, Velma

Cc: Dole, Timothy

Subject: Synergize

Hello Velma,

I am checking on the progress of the Synergize amendment. I believe Timothy mentioned that he thought it would be wrapped up this week.

Thanks for the help.

GG

**Oiguenblik, Emilia**

---

**From:** Gary E. Gaumer [gegaumer@preserveinc.com]  
**Sent:** Thursday, July 18, 2013 2:52 PM  
**To:** Noble, Velma  
**Cc:** Oiguenblik, Emilia  
**Subject:** Re: Status of REI Calculations for Synergize  
**Attachments:** Synergize Master (Fogging) PENDING 7-18-13.pdf

Hi Velma,

Thank you for the reply.

Please find the following responses to RASSB's questions:

1- The number of times that hatchery rooms are fogged varies and is specific to individual hatcheries. This is why the currently approved directions, as well as the proposed directions, state "Contact your Preserve International representative to determine the recommended fogging schedule." Preserve recommends fogging hatchery rooms on an as needed basis.

2- We have revised the Incubators and Hatchers section of the label to read:

***B) INCUBATORS AND HATCHERS:***

*Only for treatment of setters and hatchers after poultry/chicks/eggs have been removed. Not for treatment of hatchers which contain chicks/eggs. Prepare a stock solution of one (1) part Synergize to forty-two (42) parts water (3 fluid ounces Synergize to 125 fluid ounces water). Fog this solution at a rate of 3.8 ounces per 10,000 cubic feet for the fogging times specified in the chart above, into setters and hatchers immediately after transfer. Repeat daily. Discontinue hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has been exhausted. To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 solution of Synergize. If this is done, fog for 30 - 90 seconds once per hour or once every two hours.*

We have attached the label for your review.

As always, we greatly appreciate your help.

GG

---

**From:** Velma Noble <noble.velma@epa.gov>  
**Date:** Thursday, July 18, 2013 5:32 AM  
**To:** Gary Gaumer <gegaumer@preserveinc.com>  
**Cc:** "Oiguenblik, Emilia" <Oiguenblik.Emilia@epa.gov>  
**Subject:** FW: Status of REI Calculations for Synergize

Hi Gary,

Tim is finalizing his review and had a few questions. The questions are below.

---

**From:** Dole, Timothy  
**Sent:** Wednesday, July 17, 2013 4:25 PM  
**To:** Noble, Velma  
**Cc:** Leighton, Timothy; Weiss, Steven  
**Subject:** Status of REI Calculations for Synergize

Velma,

I am almost done with the assessment that is needed to approve the REI reduction; however, there are a couple of questions that need to be answered before I can finish the assessment.

Question 1: Hatchery Rooms. How often are these applications made per day and are they made every day of the week or less often? I am assuming that they are made once per day.

Question 2: Incubators and Hatchers. What is the fogging time for Incubators and Hatchers? The label indicates that the application rate is 3 ounces of fogging solution per 100 cubic feet, but it does not specify the fogging time. Since this rate is much higher than the rate of 3.8 ounces per 10,000 that is specified for Hatchery Rooms, I am assuming that the fogging times of 5 to 15 minutes listed in the table in the Hatchery Rooms section of the label do not apply to Incubators and Hatchers.

Once I get the answers to these questions I can route the memo through the review process and hopefully get it finalized in a couple of weeks.

Tim

P.S. The Synergize Label of 1.29.2013 is attached. I am assuming that this the most current version.

66171-7

**Oiguenblik, Emilia**

---

**From:** Noble, Velma  
**Sent:** Thursday, July 18, 2013 8:36 AM  
**To:** Dole, Timothy  
**Cc:** Leighton, Timothy; Weiss, Steven; Oiguenblik, Emilia  
**Subject:** RE: Status of REI Calculations for Synergize

Hi Tim.

Thanks for all of your help in getting this review done. I will talk with the registrant to get the questions answered.

---

**From:** Dole, Timothy  
**Sent:** Wednesday, July 17, 2013 4:25 PM  
**To:** Noble, Velma  
**Cc:** Leighton, Timothy; Weiss, Steven  
**Subject:** Status of REI Calculations for Synergize

Velma,

I am almost done with the assessment that is needed to approve the REI reduction; however, there are a couple of questions that need to be answered before I can finish the assessment.

Question 1: Hatchery Rooms. How often are these applications made per day and are they made every day of the week or less often? I am assuming that they are made once per day.

Question 2: Incubators and Hatchers. What is the fogging time for Incubators and Hatchers? The label indicates that the application rate is 3 ounces of fogging solution per 100 cubic feet, but it does not specify the fogging time. Since this rate is much higher than the rate of 3.8 ounces per 10,000 that is specified for Hatchery Rooms, I am assuming that the fogging times of 5 to 15 minutes listed in the table in the Hatchery Rooms section of the label do not apply to Incubators and Hatchers.

Once I get the answers to these questions I can route the memo through the review process and hopefully get it finalized in a couple of weeks.

Tim

P.S. The Synergize Label of 1.29.2013 is attached. I am assuming that this the most current version.

## **Oiguenblik, Emilia**

---

**From:** Noble, Velma  
**Sent:** Thursday, May 16, 2013 8:53 AM  
**To:** Oiguenblik, Emilia  
**Cc:** Edwards, Dennis  
**Subject:** FW: From Bruce Spielholz-Preserve International  
**Attachments:** RE: From Bruce Spielholz-Preserve International

Hi Emilia,

Please pull the jacket and the letter you sent to Preserve International. We need to let RASSB know why the notification was rejected. You can read the e-mails below.

---

**From:** Weiss, Steven  
**Sent:** Thursday, May 16, 2013 8:43 AM  
**To:** Noble, Velma  
**Cc:** Leighton, Timothy; Dole, Timothy; Edwards, Dennis  
**Subject:** RE: From Bruce Spielholz-Preserve International

Hi Velma,  
Any update on Tim's below email? Also have you had a chance?  
Thanks,  
Steve

*Bruce's  
amendment*

---

**From:** Dole, Timothy  
**Sent:** Tuesday, May 07, 2013 10:13 AM  
**To:** Weiss, Steven; Noble, Velma; Edwards, Dennis  
**Cc:** Leighton, Timothy  
**Subject:** RE: From Bruce Spielholz-Preserve International

Velma,

Did you take into consideration the email that I sent on 1/25/13? This email contained calculations that indicated that the proposed REI reduction would not trigger a risk concern. This is because the application rate was lowered to 1 in 42 and the ventilation rate was increased from 4 air changes per hour to 24 air changes per hour.

Tim

---

**From:** Weiss, Steven  
**Sent:** Tuesday, May 07, 2013 9:53 AM  
**To:** Noble, Velma; Edwards, Dennis  
**Cc:** Dole, Timothy; Leighton, Timothy  
**Subject:** FW: From Bruce Spielholz-Preserve International

Hi Velma,  
Tim Dole and I have both been contacted by Mr. Spielholz regarding a recent rejection letter that you sent to him for EPA Reg # 77171-7. Can you follow-up with him? Please let us know if there is any additional information that RASSB can provide.  
Thanks



Steve

**From:** disinfectking [mailto:disinfectking@comcast.net]  
**Sent:** Tuesday, May 07, 2013 8:54 AM  
**To:** Weiss, Steven  
**Cc:** Gary E. Gaumer  
**Subject:** Re: From Bruce Spielholz-Preserve International

Hi Steven,

Thank you for your reply.

I have attached the letter we received regarding a denial for our requested change in our product Synergize, EPA Reg. No. 66171-7, concentration application, REI and PPE.

Velma Noble is our PM.

This request was based on several factors.

We had a meeting with AMD on January 23, in which risk assessment was represented.

Our points were:

1) We wanted to lower the application rate for fogging as an "adjunct" or "supplement" to cleaning and disinfecting from the 1:4 level presently listed on fogging approved labels to 1:42.

Our contention was, since EPA does not presently have approved claims for sanitizing or disinfecting by fogging, (we are aware this is being developed), why would lowering the exposure be of concern?

IF the 1:4 "was" supposed to represent some type of efficacy as an "adjunct" or "supplement" to prior cleaning and disinfecting, Synergize had already proven to exhibit disinfecting efficacy at an application rate of 1:256, more than *5 times less* concentration than we were requesting.

**A Short Background:**

October 9, 2012, I was invited by Jeff Kempter to speak about fogging as it pertains to hatcheries at EPA AMD. I was asked to bring two other industry experts. I included Dr. Christopher Williams from Pfizer Global Animal Health, and Dr. Charles Steven Roney, representing USDA APHIS.

Since I have spent more than 30 years involved with developing disinfectant and sanitizers as we as designing fogging systems, I felt I was uniquely qualified to discuss this subject with the Agency in view of their growing interest in amending the fogging approvals for disinfectants.

It was obvious by the directions on disinfectants and sanitizers which have been in place for many years that the agency did not have a clear picture of how hatcheries function, so I brought a great deal of information to show them, and even included a video of what *real fog*, not mist or spray, looks like, and how it can be generated and applied.

I also explained the challenges we face with constant recontamination, high temperatures, and *especially* enormous air flows resulting in as many as 50 ACH.

When contacting EPA at the request of one of our customers, one of the largest poultry producers in the country, I asked Jennifer McClaine the following question:

"Dear Jennifer,

Thank you for taking the time to speak with me this morning about the various fogging uses.

I have attached our label and highlighted the area on page two relevant to my question.

Based on how we read this "NOTE:", and as this "NOTE" is specific regarding a reentry time of two (2) hours, we believe the "NOTE" refers to C) POULTRY HOUSES AND LIVESTOCK BUILDINGS and not A) HATCHERY ROOMS or B) INCUBATORS AND HATCHERS, as both A) and B) have their own recommended reentry times.

Please advise.

Thank you in advance.

Regards,

Bruce Spielholz  
Preserve International"

I received this response from Velma Noble who contacted Tim Dole about our question:

"Hi,

This is a e-mail from Tim Dole, who works in the Risk Assessment and Science Support Branch.

Velma

The product in question (Synergize, #66171-7) contains 26% ADBAC and 7% glutaraldehyde. The REI of 2 hrs is for ADBAC and it is based on a calculation of ADBAC air concentrations using a model that accounts for removal by ventilation. The initial concentration was based on the label and subsequent air concentrations were calculated using an air exchange rate of 4 air changes per hour. A similar calculation was also done for the glutaraldehyde RED and this calculation indicated that the REI should be 3 hours. Although this REI was included in the glutaraldehyde RED, the labels have not been updated to reflect REI because the glutaraldehyde DCI has not yet been issued

The REI calculations for both ADBAC and glutaraldehyde could be refined if there is information available that indicates that the air exchange rate is greater than 4 air changes per hour. The REI calculation for ADBAC could also be refined to account for particle settling (i.e. Stokes law) if the particle size distribution were known. Since glutaraldehyde is more volatile the particle settling concept does not apply.

If the REIs cannot be refined using ventilation data, then it will be necessary to measure the air concentrations directly to plot the rate of decrease for ADBAC and glutaraldehyde. This could be done by taking air samples at

specified intervals (say every 15 minutes) along with observations of control conditions such as the ventilation rate and the quality of air distribution. This could be done in an actual poultry house or it could be done in an exposure chamber. The most relevant EPA Guideline for this type of study is 875.2500 Inhalation Exposure Post Application.

Timothy Dole, CIH  
Industrial Hygienist  
Antimicrobials Division  
703-305-6450

Velma Noble---12/14/2012 02:44:29 PM---Hi, Please read the e-mail below and let me know what data is required for lowering the REI for a fo

From: Velma Noble/DC/USEPA/US  
To: Timothy Leighton/DC/USEPA/US@EPA, Timothy Dole/DC/USEPA/US@EPA  
Cc: Dennis Edwards/DC/USEPA/US@EPA  
Date: 12/14/2012 02:44 PM  
Subject: Re: From Bruce At Preserve Re: Fogging"

Tim's response is what triggered the meeting regarding our requested amendment, in which we believed we qualified every concern regarding our request.

I supplied a letter from one of the largest hatchery incubation companies in the country in which the letter (attached) explained the ACH were much greater than the agency had been previously informed, that Tim was kind enough to chart a graph in which it illustrated the application and decay rate for the actives would not present an exposure problem based on the information provided.

Further, we located PPE which had been tested and approved and would be satisfactory for REI at our requested application rate staying below the ACGIH exposure levels.

EVEN if the application remains at 1:4, Tim's chart clearly shows Synergize will still remain under the ACGIH exposure levels during fogging within 50 seconds, requiring the full mask and cartridge and under exposure levels, requiring no PPE for REI, within 8 to 9 minutes.

You were copied on Tim's letter to me of January 25 regarding this chart and your groups willingness to help.

Steven, the agency clearly has issues with fogging directions. We understand this and have attempted to shed light on areas of our industry concern.

We were not let do believe and do not believe the "new" fogging directives, which have not yet been placed due to lack of available protocols should hinder our efforts to provide the most effective and safest means of providing this application to our customers.

Note: To further illustrate any concern regarding efficacy at our 1:42 requested application rate, I brought several hundred poultry company and state performed bacteria and mold plates to show the efficacy of Synergize at this rate. These plates did not show a reduction of bacteria and molds, but a complete elimination.

I am appealing to you to please assist in this as our industry will opt to use formaldehyde, which presents an entire new set of problems, due to labeling which does not require SCBA.

The REI and the PPE are so restrictive regarding the present fogging directions for disinfectants and sanitizers, they will go the "formaldehyde" route.

I assure you, after being in hundreds of hatcheries using formaldehyde, anyone at your agency would *much rather* opt for the fogging directions we are suggesting.

Thank you in advance and *again* sorry for the "longwind", but I thought this explanation would help you make a decision.

Kindest regards,

Bruce Spielholz/Preserve International

**From:** Weiss, Steven

**Sent:** Monday, May 06, 2013 5:54 PM

**To:** disinfecting

**Subject:** RE: From Bruce Spielholz-Preserve International

Hi Bruce,

I got your voice msg about the amendment letter you just received. Sorry I have been in mtgs all day and I am headed out the door now. Can you send a copy of the letter? Who is the Product Manager (PM)?

Thanks,

Steve

---

Steven H. Weiss  
Chief, Risk Assessment and Science Support Branch  
Antimicrobials Division  
Office of Pesticide Programs  
US Environmental Protection Agency  
Weiss.Steven@epa.gov  
(703)308-8293

## Oiguenblik, Emilia

---

**From:** Noble, Velma  
**Sent:** Tuesday, July 16, 2013 10:59 AM  
**To:** Oiguenblik, Emilia  
**Subject:** FW: new Bean for TimD DP 412813 (66171-7 SYNERGIZE)

Hi,

Please print and keep for your records.

---

**From:** Layton, Zoe  
**Sent:** Tuesday, July 16, 2013 9:39 AM  
**To:** Weiss, Steven  
**Cc:** Dole, Timothy; Noble, Velma  
**Subject:** RE: new Bean for TimD DP 412813 (66171-7 SYNERGIZE)

This has been assigned to Tim Dole in OPPIN

PMs: Please remember to enter the MRID #s into OPPIN when assigning RASSB BEANs.

Zoë Layton  
Risk Assessment and Science Support Branch (RASSB)  
Antimicrobials Division (AD)  
Office of Pesticide Programs (OPP)  
U.S. Environmental Protection Agency  
p. 703.308.0440  
e. [Layton.Zoe@epa.gov](mailto:Layton.Zoe@epa.gov)



---

**From:** Weiss, Steven  
**Sent:** Monday, July 01, 2013 9:24 AM  
**To:** Layton, Zoe  
**Cc:** Dole, Timothy; Noble, Velma  
**Subject:** new Bean for TimD DP 412813 (66171-7 SYNERGIZE)

Zoe-  
please assign DP 412813 to Tim. The due date is Apr 7, 2014 but he can finish sooner if his workload permits.  
Thanks,  
Steve

RASSB Staff	Ingredient Name	PC Code	Registration #	RASSB Due Date	PRIA Due Date/Docket Open
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Dole, Tim

Glutaraldehyde, Alkyl\* dimethyl  
benzyl ammonium chloride  
\*(67%C12, 25%C14, 7%C16, 1%C18)

043901, 66171-7  
069175

4/7/14

4/7/14

P

## Oiguenblik, Emilia

---

**From:** Noble, Velma  
**Sent:** Wednesday, August 07, 2013 9:25 AM  
**To:** Oiguenblik, Emilia  
**Subject:** FW: Synergize

Let's try to wrap this one up. A572 - 66171-7

-----Original Message-----

**From:** Gary Gaumer [<mailto:gegaumer@preserveinc.com>]  
**Sent:** Tuesday, July 30, 2013 5:20 PM  
**To:** Noble, Velma  
**Cc:** Dole, Timothy  
**Subject:** Synergize

Hello Velma,

I am checking on the progress of the Synergize amendment. I believe Timothy mentioned that he thought it would be wrapped up this week.

Thanks for the help.

GG



✓ **World Headquarters** P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607  
**Tennessee Operation** 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446  
**California Operation** 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

April 30, 2013

VIA Certified Mail - Return Receipt Number 7008 1140 0003 3182 6336

Ms. Velma Noble  
U.S. Environmental Protection Agency  
Document Processing Desk  
Office of Pesticide Programs (7504P)  
1200 Pennsylvania Avenue, N.W.  
Washington DC 20460-0001

Re: Response to April 1, 2013 EPA letter on fogging data

Dear Ms. Noble:

This letter is in response to the EPA's April 1, 2013 letter requesting Preserve International's intentions regarding the submission of data to support the fogging claim for our product Synergize, EPA registration number 66171-7.

Preserve International intends to generate the necessary data to support the fogging claim. We have already begun the process of working with the science branch to develop a protocol that the EPA will accept.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,  
Preserve International

  
Gary E. Gaumer  
President

Team 31



my

# Fee for Service

{936796b~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies?      ☐ Fee Waiver?  
☐ volpay    % Reduction: \_\_\_\_

for Division

- ☒ AD
- ☐ BPPD
- ☐ RD

Risk Mgr.    31

Receipt No.

S- 936796

EPA File Symbol/Reg. No.

66171-7

Pin-Punch Date:

6/14/2013

☐ This item is NOT subject to FFS action.

## Action Code:

Requested:

A572

Granted:

A572

Amount Due: \$ 11,996.00

## Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Team 2

Date: 06-17-13

Remarks:



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

June 17, 2013

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-479830  
EPA File Symbol or Registration Number: 66171-7  
Product Name: SYNERGIZE  
EPA Receipt Date: 14-Jun-2013  
EPA Company Number: 66171  
Company Name: PRESERVE INTERNATIONAL

GARY GAUMER  
PRESERVE INTERNATIONAL  
PO Box 17003  
RENO, NV 89511-

SUBJECT: Receipt of Amendment and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your amendment, 75% small business waiver request, and certification of payment. If you submitted data with this amendment, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code A572:  
NEW PRODUCT OR AMENDMENT REQUIRING DATA REVIEW FOR RISK  
ASSESSMENT BY SCIENCE BRANCH (E.G., CHANGES TO REI, OR PPE, OR USE  
RATE);

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

A handwritten signature in black ink, appearing to be "m. jk".

Front End Processing Staff  
Information Technology & Resources Management Division



## Online Payment

## Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

## Pay.gov Tracking Information

Application Name: PRIA Service Fees

Pay.gov Tracking ID: 25B2IRMD

Agency Tracking ID: 74459999950

Transaction Date and Time: 06/06/2013 13:29 EDT

## Payment Summary

## Address Information

Account Holder Gary  
Name: Gaumer  
PO Box

Billing Address: 3135

Billing Address 2:

City:

State / Province:

Zip / Postal Code:

Country: USA

## Account Information

American

Card Type: Express

Card Number: \*\*\*\*\*2007

Decision  
Number:Registration  
Number: 66171-7

Preserve

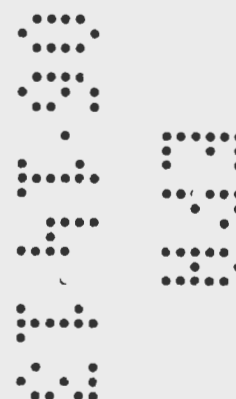
Company Name: International

Company  
Number: 66171

Action Code: A572

## Payment Information

Payment Amount: \$2,999.00

Transaction Date 06/06/2013  
and Time: 13:29 EDT



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

June 21, 2013

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

PRESERVE INTERNATIONAL  
PO.BOX : 17003  
RENO, NV 89511

**Report of Analysis for Compliance with PR Notice 11-03**

Thank you for your submittal of 14-JUN-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

# Receipt for Section 3

S: 936796

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 66171 PRESERVE INTERNATIONAL

V

Print Letter

Enter More Information

Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 31

Product #: 66171-7 Product Name: SYNERGIZE

Override#:

Me Too

Me Too

Section3:

Product Name:

Application Date: 13-Jun-2013

ie

OPP Rec'd Date: 14-Jun-2013

ie

Front End Date: 14-Jun-2013

ie

Risk Manager Send Date:

ie

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Follow up to Jan submission. Study with Air concentrations for hatchery fogging

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Des

Study

View/Edit

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 6-14-13

Experts In-Processing Signature: B.B.

Date 6-18-13

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>66171-7</u>		EPA Receipt Date: <u>6-14-13</u>					
Items for Review					Yes	No	N/A*
1	<b>Application Form</b> (EPA Form 8570-1) signed & complete including package type				<input checked="" type="checkbox"/>		
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4)						<input checked="" type="checkbox"/>
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no				
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) completed and signed (N/A if 100% repack)				<input checked="" type="checkbox"/>		
	Certificate and data matrix consistent				<input checked="" type="checkbox"/>		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no				
	If applicable, is there a letter of Authorization for exclusive use only.						
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)						<input checked="" type="checkbox"/>
	<b>Data Matrix</b> (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)				<input checked="" type="checkbox"/>		
5	a) Selective Method (Fee category experts use)	<input checked="" type="checkbox"/>	<input type="checkbox"/>				
	b) Cite-All (Fee category experts use)	<input type="checkbox"/>	<input type="checkbox"/>				
	c) Applicant owns all data (Fee category experts use)	<input type="checkbox"/>	<input type="checkbox"/>				
6	<b>5 Copies of Label</b> ( <u>Electronic labels on CD</u> are encouraged and guidance is available)					<input checked="" type="checkbox"/>	
7	<b>Is the data package consistent with PR Notice 86-5</b>				<input checked="" type="checkbox"/>		
8	<b>Notice of Filing</b> included with petitions						<input checked="" type="checkbox"/>

## Unugboji, Wilkinson

---

**From:** Gary E. Gaumer [gegaumer@preserveinc.com]  
**Sent:** Wednesday, June 19, 2013 2:04 PM  
**To:** Unugboji, Wilkinson  
**Subject:** Re: EPA Product Update for Synergize  
**Attachments:** Synergize Package.pdf

Thank you for contacting me.

The documents you request are attached.

Thank you,

GG

---

**From:** "Unugboji, Wilkinson" <[Unugboji.Wilkinson@epa.gov](mailto:Unugboji.Wilkinson@epa.gov)>  
**Date:** Wednesday, June 19, 2013 10:33 AM  
**To:** Gary Gaumer <[gegaumer@preserveinc.com](mailto:gegaumer@preserveinc.com)>  
**Subject:** EPA Product Update for Synergize

Mr. Gaumer,

Please be informed that we have concluded our preliminary review of the package sent in support of the amended registration of Synergize (66171-7). See deficiency below:

- Application package is missing an application form (8570-1), certification with respect to citation of data (8570-34) and data matrix (external and internal use) (8570-35).

Please email me the missing documents. The deadline for submitting the requested documents is 06/28/13. Feel free to contact me if you have any question.

*Regards,*

Unugboji Wilkinson  
Data Analyst - Indus/EPA Contractor  
One Potomac Yard  
2777 S.Crystal Drive, S-4813  
Arlington, VA 22202  
Tel:(703).347.8518  
Fax:(703)305.5060  
EPA mail: [unugboji.wilkinson@epa.gov](mailto:unugboji.wilkinson@epa.gov)



9	If applicable for conventional applications, <u>reduced risk rationale</u>				X
	<u>Required Data</u> and/or data waivers. See Footnote C.				
10	a) List study (or studies) not included with application				

Comments:

- X Application Form, Cert. with Respect to Cit. and Data matrix are missing. Requestant contacted 06/19/2013
- X Requested missing forms have been provided.
- X Data package approved
- X Ticket approved.

MND:491531

IK 703-347-8518

\* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, **to obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### **Conventional New Product Applications**

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

## Memorandum

Date: 6 / 24 / 13

To: Ph 31, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission



✓ **World Headquarters** P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607  
**Tennessee Operation** 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446  
**California Operation** 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

June 13, 2013

Ms. Velma Noble  
Office of Pesticides Programs (7504C)  
United States Environmental Protection Agency (AMEND)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Re: Synergize, EPA Registration Number 66171-7

Dear Ms. Noble:

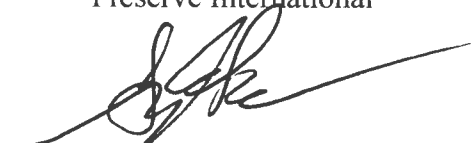
Preserve International hereby submits this data as a follow-up to our amendment application that was submitted on January 30, 2013.

Included in this submission are the following:

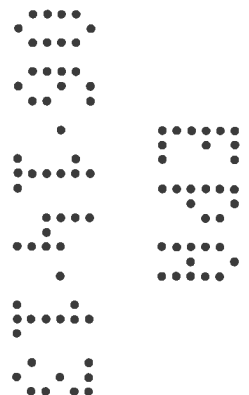
- 1) Three copies of the data.
- 2) Receipt showing payment for the PRIA3 fees.

We thank you for your help in this process.

Sincerely,  
Preserve International



Gary E. Gaumer  
President



✓ **World Headquarters** P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607  
**Tennessee Operation** 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446  
**California Operation** 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

June 13, 2013

Ms. Velma Noble  
Office of Pesticides Programs (7504C)  
United States Environmental Protection Agency (AMEND)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Re: Synergize, EPA Registration Number 66171-7

Dear Ms. Noble:

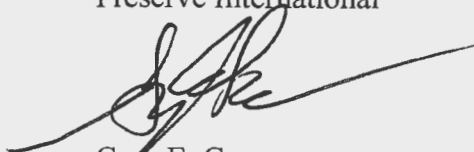
Preserve International hereby submits this data as a follow-up to our amendment application that was submitted on January 30, 2013.

Included in this submission are the following:

- 49153101** 1) Three copies of the data.  
2) Receipt showing payment for the PRIA3 fees.

We thank you for your help in this process.

Sincerely,  
Preserve International



Gary E. Gaumer  
President



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 66171-7	2. EPA Product Manager Ms. Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Synergize	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Preserve International PO Box 17003 Reno, NV 89511  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)  
Data submission for glutaraldehyde air concentrations for hatchery tagging.

## Section - III

1. Material This Product Will Be Packaged In:			
Child Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 275g, 250g, 55g, 30g, 15g, 5g, 4x1g	5. Location of Label Directions <input checked="" type="checkbox"/> On Label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other Sleeve	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Gary Gaumer	Title President	Telephone No. (Include Area Code) 775-853-9776	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title President		
4. Typed Name Gary Gaumer	5. Date June 19, 2013		





www.PreserveInternational.com

✓ **World Headquarters** P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607  
**Tennessee Operation** 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446  
**California Operation** 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

January 30, 2013

Ms. Velma Noble  
Office of Pesticides Programs (7504C)  
United States Environmental Protection Agency (AMEND)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Re: Synergize, EPA Registration Number 66171-7

Dear Ms. Noble:

Preserve International hereby submits this amendment to revise the fogging directions for hatchery rooms, incubators and hatchers, and poultry houses and livestock buildings for our product, Synergize, EPA registration number 66171-7.

Included in this submission are the following:

- 1) Application For Pesticide, EPA Form 8570-1
- 2) Five separate printouts documenting the appropriate re-entry times for the various air exchanges listed on the proposed label. These reports are prints developed using the spreadsheet provided by Mr. Timothy Dole, Industrial Hygienist, Antimicrobials Division.
- 3) Five copies of the proposed label.

We thank you for your help in this process.

Sincerely,  
Preserve International



Gary E. Gaumer  
President

*"The Solution is Preserve"*



States  
**Environmental Protection Agency**  
 Washington, DC 20460

☒ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 66171-7	2. EPA Product Manager Ms. Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Synergize	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Preserve International PO Box 17003 Reno, NV 89511 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

### Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

Revision of fogging directions for hatchery rooms, incubators and hatchers, and poultry houses and livestock buildings.

### Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Gary Gaumer	Title President	Telephone No. (Include Area Code) 775-853-9776
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		K. Data Application Received (Stamped)
2. Signature 	3. Title President	
4. Typed Name Gary Gaumer	5. Date January 30, 2013	

# Material Sent for Data Extraction

Reg # 66171-7

Description: \_\_\_\_\_

☒ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated \_\_\_\_\_

☐ Notification Dated \_\_\_\_\_

☒ New CSF(s) Dated 4/12/13

☐ Other: \_\_\_\_\_

☒ Decision #: 477393

☐ Other Action/Comments: \_\_\_\_\_

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: E. Oiguenb1.2

Phone: 347-0199 Division: AD

Date: \_\_\_\_\_

Created February 3, 2011

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Gary E. Gaumer  
Preserve International  
P.O. Box 17003  
Reno NV 89511

JUN 18 2013

SUBJECT: Synergize  
EPA Registration Number: 66171-7  
Application Dated: March 21, 2013  
Receipt Dated: March 27, 2013

Dear Mr. Gaumer:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable.

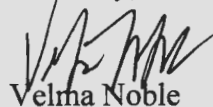
- Submission of additional Alternate Formula..

Product Science Branch of Antimicrobial Division finds the CSF for alternate formulation dated 04/12/13 to be acceptable. For details see attached associated Chemistry Review.

**General Comments**

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Attachment: Chemistry Review

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

**Noble, Velma**

---

**From:** Edwards, Dennis  
**Sent:** Thursday, June 06, 2013 8:40 AM  
**To:** Gary E. Gaumer; Noble, Velma  
**Subject:** RE: Synergize Fogging

Hi Gary,

Velma and I discussed the January 30, 2013 submission from Preserve International and our April 29, 2013 response to the submission. I will lay out our process.

The January 30, 2013 application was submitted to revise fogging directions for hatchery rooms, incubators, hatcheries, poultry houses and livestock buildings. Specifically, you are attempting to add re-entry times based on air exchanges and use rate/time. Several one page reports were provided which are based on a spreadsheet provided to Preserve International by Tim Dole, a RASSB scientist. Since you are proposing different re-entry times and have provided reports (data) to support the proposed re-entry times, this information needs to be reviewed by our scientists to confirm that your proposal is acceptable and that there are no errors in the calculations or assumptions. Thus, the application should have been submitted as a PRIA amendment (A572) since data/information were provided to support the proposed change. I realize that there were prior discussions and e-mail exchanges with the Agency on this matter and you believe that the re-entry proposal submitted is acceptable based on those discussions, but, the application and associated data must still be reviewed. Our April 29 response did not state that the proposed re-entry intervals were unacceptable just that the application needed to be resubmitted as a PRIA application with the appropriate registration fee.

There is a 9 month review time line associated with PRIA category A572. Again, we realize there were prior discussions with AD before you submitted this application which should then allow the proposed re-entry times to be accepted. While that appears reasonable, we just need the assumptions and information confirmed. Once this application is resubmitted as a PRIA application we will endeavor to work with science branch to review this information as quickly as we can recognizing that much of the work was completed using our guidance.

If you have further questions please let me know.

Dennis

---

**From:** Gary E. Gaumer [<mailto:gegaumer@preserveinc.com>]  
**Sent:** Wednesday, June 05, 2013 4:34 PM  
**To:** Noble, Velma  
**Cc:** Edwards, Dennis  
**Subject:** Synergize Fogging

Hello,

I apologize if you are receiving this message twice, but we are having an issue with our email server. Many of our emails are getting bounced back, and this was one of them..

Thank you for your help.

GG

---

**From:** Gary Gaumer <[gegaumer@preserveinc.com](mailto:gegaumer@preserveinc.com)>  
**Date:** Wednesday, June 5, 2013 9:41 AM  
**To:** Velma Noble <[noble.velma@epa.gov](mailto:noble.velma@epa.gov)>  
**Cc:** "Edwards, Dennis" <[Edwards.Dennis@epa.gov](mailto:Edwards.Dennis@epa.gov)>  
**Subject:** Re: Synergize Fogging

Hello,

We eagerly look forward to Dennis' reply.

Thank you,

GG

---

**From:** Velma Noble <[noble.velma@epa.gov](mailto:noble.velma@epa.gov)>  
**Date:** Wednesday, June 5, 2013 6:42 AM  
**To:** Gary Gaumer <[gegaumer@preserveinc.com](mailto:gegaumer@preserveinc.com)>  
**Cc:** "Edwards, Dennis" <[Edwards.Dennis@epa.gov](mailto:Edwards.Dennis@epa.gov)>  
**Subject:** RE: Synergize Fogging

Hi,

Dennis will follow-up with a e-mail. Thanks

---

**From:** Gary E. Gaumer [<mailto:gegaumer@preserveinc.com>]  
**Sent:** Monday, June 03, 2013 6:18 PM  
**To:** Noble, Velma  
**Cc:** Edwards, Dennis  
**Subject:** Synergize Fogging

Hi Velma,

You asked me to contact you after your 8:00am meeting with Dennis Edwards, to see where we are at with respect to the fogging amendment we currently have pending at the EPA.

I am following-up with that request.

Thank you for your help,

GG

„Error! Filename not specified.“

**Noble, Velma**

---

**From:** disinfectking [disinfectking@comcast.net]  
**Sent:** Monday, May 20, 2013 9:03 AM  
**To:** Noble, Velma  
**Cc:** Gary E. Gaumer; Swindell, Marshall; Dole, Timothy; Edwards, Dennis; Weiss, Steven  
**Subject:** From Bruce Spielholz-Preserve International RE: SYNERGIZE

Dear Velma,

Please advise status of our Synergize label as per Stevens email below.

Thank you in advance.

Kindest regards,

Bruce Spielholz  
Preserve International  
Regulatory Affairs

Phone: (404) 683-9659  
Email: disinfectking@comcast.net

From: Weiss, Steven <mailto:Weiss.Steven@epa.gov>  
Sent: Thursday, May 09, 2013 5:11 PM  
To: disinfectking <mailto:disinfectking@comcast.net>  
Cc: Gary E. Gaumer <mailto:gegaumer@preserveinc.com> ; Swindell, Marshall <mailto:Swindell.Marshall@epa.gov> ; Noble, Velma <mailto:Noble.Velma@epa.gov> ; Dole, Timothy <mailto:Dole.Timothy@epa.gov> ; Edwards, Dennis <mailto:Edwards.Dennis@epa.gov>  
Subject: RE: From Bruce Spielholz-Preserve International

Hi Bruce,

We are working on a response to your below email regarding Synergize. Tim Dole also indicated that you have called and e-mailed him regarding other issues including another product SILOXYCIDE/Sanosil HWP. The product managers (PMs) for these products will follow-up you as soon possible. I think Velma is out of the office until 5/14/13.

For future please contact the PMs with your registration questions or concerns, not RASSB staff. Its OK to Cc RASSB on email communications. We are happy to help but this the most efficient process for us.

Thanks,

Steve



---

Steven H. Weiss

Chief, Risk Assessment and Science Support Branch Antimicrobials Division Office of Pesticide Programs US Environmental Protection Agency Weiss.Steven@epa.gov  
(703)308-8293

From: disinfectking [mailto:disinfectking@comcast.net]  
Sent: Tuesday, May 07, 2013 8:54 AM  
To: Weiss, Steven  
Cc: Gary E. Gaumer  
Subject: Re: From Bruce Spielholz-Preserve International

Hi Steven,

Thank you for your reply.

I have attached the letter we received regarding a denial for our requested change in our product Synergize, EPA Reg. No. 66171-7, concentration application, REI and PPE.

Velma Noble is our PM.

This request was based on several factors.

We had a meeting with AMD on January 23, in which risk assessment was represented.

Our points were:

1) We wanted to lower the application rate for fogging as an "adjunct" or "supplement" to cleaning and disinfecting from the 1:4 level presently listed on fogging approved labels to 1:42.

Our contention was, since EPA does not presently have approved claims for sanitizing or disinfecting by fogging, (we are aware this is being developed), why would lowering the exposure be of concern?

IF the 1:4 "was" supposed to represent some type of efficacy as an "adjunct" or "supplement" to prior cleaning and disinfecting, Synergize had already proven to exhibit disinfecting efficacy at an application rate of 1:256, more than 5 times less concentration than we were requesting.

#### A Short Background:

October 9, 2012, I was invited by Jeff Kempter to speak about fogging as it pertains to hatcheries at EPA AMD. I was asked to bring two other industry experts. I included Dr. Christopher Williams from Pfizer Global Animal Health, and Dr. Charles Steven Roney, representing USDA APHIS.

Since I have spent more than 30 years involved with developing disinfectant and sanitizers as we as designing fogging systems, I felt I was uniquely qualified to discuss this subject with the Agency in view of their growing interest in amending the fogging approvals for disinfectants.

It was obvious by the directions on disinfectants and sanitizers which have been in place for many years that the agency did not have a clear picture of how hatcheries function, so I brought a great deal of information to show them, and even included a video of what real fog, not mist or spray, looks like, and how it can be generated and applied.

I also explained the challenges we face with constant recontamination, hard waters, and especially enormous air flows resulting in as many as 50 ACH.

When contacting EPA at the request of one of our customers, one of the largest poultry producers in the country, I asked Jennifer McClaine the following question:

"Dear Jennifer,

Thank you for taking the time to speak with me this morning about the various fogging uses.

I have attached our label and highlighted the area on page two relevant to my question.

Based on how we read this "NOTE:", and as this "NOTE" is specific regarding a reentry time of two (2) hours, we believe the "NOTE" refers to C) POULTRY HOUSES AND LIVESTOCK BUILDINGS and not A) HATCHERY ROOMS or

B) INCUBATORS AND HATCHERS, as both A) and B) have their own recommended reentry times.

Please advise.

Thank you in advance.

Regards,

Bruce Spielholz

Preserve International"

I received this response from Velma Noble who contacted Tim Dole about our question:

"Hi,

This is a e-mail from Tim Dole, who works in the Risk Assessment and Science Support Branch.

Velma

The product in question (Synergize, #66171-7) contains 26% ADBAC and 7% glutaraldehyde. The REI of 2 hrs is for ADBAC and it is based on a calculation of ADBAC air concentrations using a model that accounts for removal by ventilation. The initial concentration was based on the label and subsequent air concentrations were calculated using an air exchange rate of 4 air changes per hour. A similar calculation was also done for the glutaraldehyde RED and this calculation indicated that the REI should be 3 hours. Although this REI was included in the glutaraldehyde RED, the labels have not been updated to reflect REI because the glutaraldehyde DCI has not yet been issued

The REI calculations for both ADBAC and glutaraldehyde could be refined if there is information available that indicates that the air exchange rate is greater than 4 air changes per hour. The REI calculation for ADBAC could also be refined to account for particle settling (i.e. Stokes law) if the particle size distribution were known. Since glutaraldehyde is more volatile the particle settling concept does not apply.

If the REIs cannot be refined using ventilation data, then it will be necessary to measure the air concentrations directly to plot the rate of decrease for ADBAC and glutaraldehyde. This could be done by taking air samples at specified intervals (say every 15 minutes) along with observations of controlling conditions such as the ventilation rate and the quality of air distribution. This could be done in an actual poultry house or it could be done in an exposure chamber. The most relevant EPA Guideline for this type of study is 875.2500 Inhalation Exposure Post Application.

Timothy Dole, CIH  
Industrial Hygienist

Antimicrobial Division  
703-305-6450

Velma Noble---12/14/2012 02:44:29 PM---Hi, Please read the e-mail below and let me know what data is required for lowering the REI for a fo

From: Velma Noble/DC/USEPA/US  
To: Timothy Leighton/DC/USEPA/US@EPA, Timothy Dole/DC/USEPA/US@EPA  
Cc: Dennis Edwards/DC/USEPA/US@EPA  
Date: 12/14/2012 02:44 PM  
Subject: Re: From Bruce At Preserve Re: Fogging"

Tim's response is what triggered the meeting regarding our requested amendment, in which we believed we qualified every concern regarding our request.

I supplied a letter from one of the largest hatchery incubation companies in the country in which the letter (attached) explained the ACH were much greater than the agency had been previously informed, that Tim was kind enough to chart a graph in which it illustrated the application and decay rate for the actives would not present an exposure problem based on the information provided.

Further, we located PPE which had been tested and approved and would be satisfactory for REI at our requested application rate staying below the ACGIH exposure levels.

EVEN if the application remains at 1:4, Tim's chart clearly shows Synergize will still remain under the ACGIH exposure levels during fogging within 50 seconds, requiring the full mask and cartridge and under exposure levels, requiring no PPE for REI, within 8 to 9 minutes.

You were copied on Tim's letter to me of January 25 regarding this chart and your groups willingness to help.

Steven, the agency clearly has issues with fogging directions. We understand this and have attempted to shed light on areas of our industry concern.

We were not let do believe and do not believe the "new" fogging directives, which have not yet been placed due to lack of available protocols should hinder our efforts to provide the most effective and safest means of providing this application to our customers.

Note: To further illustrate any concern regarding efficacy at our 1:42 requested application rate, I brought several hundred poultry company and state performed bacteria and mold plates to show the efficacy of Synergize at this rate. These plates did not show a reduction of bacteria and molds, but a complete elimination.

I am appealing to you to please assist us in this as our industry will opt to using formaldehyde, which presents an entire new set of problems, due to labeling which does not require SCBA.

The REI and the PPE are so restrictive regarding the present fogging directions for disinfectants and sanitizers, they will go the "formaldehyde" route.

I assure you, after being in hundreds of hatcheries using formaldehyde, anyone at your agency would much rather opt for the fogging directions we are suggesting.

Thank you in advance and again sorry for the "longwind", but I thought this explanation would help you make a decision.

Kindest regards,

Bruce Spielholz/Preserve International

From: Weiss, Steven <mailto:Weiss.Steven@epa.gov>

Sent: Monday, May 06, 2013 5:54 PM

To: disinfectking <mailto:disinfectking@comcast.net>

Subject: RE: From Bruce Spielholz-Preserve International

Hi Bruce,

I got your voice msg about the amendment letter you just received. Sorry I have been in mtgs all day and I am headed out the door now. Can you send a copy of the letter? Who is the Product Manager (PM)?

Thanks,

Steve

---

Steven H. Weiss

Chief, Risk Assessment and Science Support Branch Antimicrobials Division Office of Pesticide Programs US Environmental Protection Agency Weiss.Steven@epa.gov  
(703)308-8293

## **Oiguenblik, Emilia**

---

**From:** Noble, Velma  
**Sent:** Thursday, May 16, 2013 8:53 AM  
**To:** Oiguenblik, Emilia  
**Cc:** Edwards, Dennis  
**Subject:** FW: From Bruce Spielholz-Preserve International  
**Attachments:** RE: From Bruce Spielholz-Preserve International

Hi Emilia,

Please pull the jacket and the letter you sent to Preserve International. We need to let RASSB know why the notification was rejected. You can read the e-mails below.

---

**From:** Weiss, Steven  
**Sent:** Thursday, May 16, 2013 8:43 AM  
**To:** Noble, Velma  
**Cc:** Leighton, Timothy; Dole, Timothy; Edwards, Dennis  
**Subject:** RE: From Bruce Spielholz-Preserve International

Hi Velma,  
Any update on Tim's below email? Also have you had a chance to follow-up with Mr. Spielholz?  
Thanks,  
Steve

---

**From:** Dole, Timothy  
**Sent:** Tuesday, May 07, 2013 10:13 AM  
**To:** Weiss, Steven; Noble, Velma; Edwards, Dennis  
**Cc:** Leighton, Timothy  
**Subject:** RE: From Bruce Spielholz-Preserve International

Velma,

Did you take into consideration the email that I sent on 1/25/13? This email contained calculations that indicated that the proposed REI reduction would not trigger a risk concern. This is because the application rate was lowered to 1 in 42 and the ventilation rate was increased from 4 air changes per hour to 24 air changes per hour.

Tim

---

**From:** Weiss, Steven  
**Sent:** Tuesday, May 07, 2013 9:53 AM  
**To:** Noble, Velma; Edwards, Dennis  
**Cc:** Dole, Timothy; Leighton, Timothy  
**Subject:** FW: From Bruce Spielholz-Preserve International

Hi Velma,  
Tim Dole and I have both been contacted by Mr. Spielholz regarding a recent rejection letter that you sent to him for EPA Reg # 77171-7. Can you follow-up with him? Please let us know if there is any additional information that RASSB can provide.  
Thanks

Steve

---

**From:** disinfectking [mailto:disinfectking@comcast.net]  
**Sent:** Tuesday, May 07, 2013 8:54 AM  
**To:** Weiss, Steven  
**Cc:** Gary E. Gaumer  
**Subject:** Re: From Bruce Spielholz-Preserve International

Hi Steven,

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This request was based on several factors.

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Kindest regards,

Bruce Spielholz/Preserve International

**From:** Weiss, Steven

**Sent:** Monday, May 06, 2013 5:54 PM

**To:** disinfecting

**Subject:** RE: From Bruce Spielholz-Preserve International

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Steve

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Steven H. Weiss  
Chief, Risk Assessment and Science Support Branch  
Antimicrobials Division  
Office of Pesticide Programs  
US Environmental Protection Agency  
Weiss.Steven@epa.gov  
(703)308-8293



✓ **World Headquarters** P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607  
**Tennessee Operation** 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446  
**California Operation** 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

April 30, 2013

VIA Certified Mail - Return Receipt Number 7008 1140 0003 3182 6336

Ms. Velma Noble  
U.S. Environmental Protection Agency  
Document Processing Desk  
Office of Pesticide Programs (7504P)  
1200 Pennsylvania Avenue, N.W.  
Washington DC 20460-0001

Re: Response to April 1, 2013 EPA letter on fogging data

Dear Ms. Noble:

This letter is in response to the EPA's April 1, 2013 letter requesting Preserve International's intentions regarding the submission of data to support the fogging claim for our product Synergize, EPA registration number 66171-7.

Preserve International intends to generate the necessary data to support the fogging claim. We have already begun the process of working with the science branch to develop a protocol that the EPA will accept.

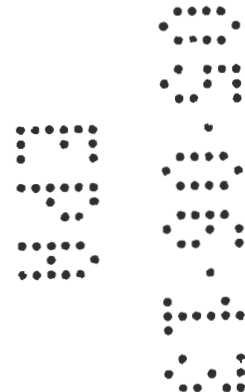
If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,  
Preserve International

  
Gary E. Gaumer  
President

Team 31



# Material Sent for Data Extraction

Reg # 66171-7

Description: Return Jacket

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated \_\_\_\_\_

☐ Notification Dated \_\_\_\_\_

☐ New CSF(s) Dated \_\_\_\_\_

☐ Other: \_\_\_\_\_

☐ Decision #: \_\_\_\_\_

☐ Other Action/Comments: \_\_\_\_\_

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: D Capone

Phone: \_\_\_\_\_ Division: AD

Date: 4/29/13

Created February 3, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 29 2013

Mr. Gary Gaumer  
President  
Preserve International  
PO Box 17003  
Reno, NV 89511

Subject: **Synergize**  
EPA Registration Number 66171-7  
Application Dated January 30, 2013  
EPA Received Date February 4, 2013

Dear Ms. Gaumer:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is unacceptable for the following.

**Proposed Amendment:**

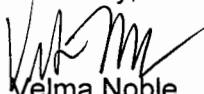
- Revised labeling

The amendment application to revise your fogging directions for hatchery rooms, incubators and hatchers, poultry houses and livestock buildings needs to be resubmitted as a PRIA amendment. The PRIA code would be A572. The reason that it would be a PRIA is there is data that must be reviewed to support your proposed reentry changes. The data need to be formatted properly so it can receive an MRID number.

**General Comments:**

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224 or Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460


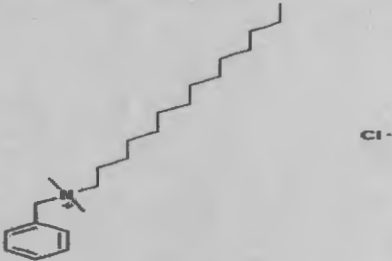


United States  
Environmental Protection  
Agency

**Office of Pesticide Programs**

**Antimicrobials Division (AD)**

April 16, 2013.

EPA Reg#: 66171-7.		DP Barcode: 410909.	
		Submission #: 933371.	
Product name: <b>Synergize.</b>		Registrant: Preserve International.	
Reviewer's name: Salvador Rodriguez		AD/PSB/CTT- Product Chemistry	
Agency due date: 06/25/13.		PSB received date: 04/10/13.	
CTT received date: 04/10/13.		Science due date: 05/11/13.	
Formulation type EUP.			
Integrated system: <input checked="" type="checkbox"/>		Non integrated system: <input type="checkbox"/>	Food use: <input type="checkbox"/> Non food use: <input checked="" type="checkbox"/>
Action Code: 362.		Date Completed: 04/16/13.	
PC Code(s)	CAS #(s)	Active Ingredient Names	% wt (label)
043901	111-30-8	Glutaraldehyde	7.00
			
069175	68391-01-5	Alkyl dimethyl benzyl ammonium chloride	26.00
			
Test Lab: N/A.			
MRID(s): N/A.			
Approver: Karen P. Hicks		Approved date: 04/16/13.	
Guideline: Formulation.			
Comments:			

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

**Office of Pesticide Programs**

**Antimicrobials Division (AD)**

April 16, 2013.

**MEMORANDUM**

**Subject:** Product Chemistry Review for EPA Reg # 66171-7

**From:** Salvador Rodríguez, Chemist  
Product Science Branch, CT Team  
Antimicrobials Division (7510P)

**Thru:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
Antimicrobials Division (7510P)

**To:** Velma Noble/ Emilia Oiguenblik.  
PM Team 31  
Antimicrobials Division (7510P)

**APPLICANT:** Preserve International.

**Action code:** 362

**Due date:** 06/25/03.

**Product Formulation**  
**Active Ingredient(s)**

**% by wt.**

Alkyl dimethyl benzyl ammonium chloride .....26.00

Glutaraldehyde.....7.00

66171-7\_D410909\_\_PreserveInternational

## BACKGROUND:

The registrant, Preserve International, has submitted a CSF for the alternate (synergize-NP-NF) formulation, to support the application for the disinfectant, fungicide and virucide, integrated, non-food, and end-use product, **Synergize**. The registrant is adding a new fragrance to the formulation. Product Chemistry Reviewer has received the following documents:

- A letter dated, 03/21/13.
- Confidential Statement of Formula (CSF) dated 03/21/13, for alternate (synergize-NP-NF) formulation.
- Confidential Statement of Formula (CSF), dated 09/11/2003, for the basic formulation.
- Confidential Statement of Formula, dated 04/12/13, for the alternate (synergize-NP-NF) formulation.
- Formulator's Exemption Statement dated 03/21/13.

## FINDINGS:

1. The CSF, dated 03/21/13, for the alternate (synergize-NP-NF) formulation is obsolete
2. The CSF, dated 04/12/13, for the alternate (synergize-NP-NF) formulation is revised.
3. The CSF, dated 09/11/13, for the basic formulation is used as reference.
4. The CSF and the label have the same nominal.
5. All certified limits meet the EPA standard certified limits.

## CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the (CSFs), dated 04/12/13, for the alternate (synergize-NF-NP) formulation for the non-integrated, non-food and end-use product EPA Reg. No. 66171-7 to be acceptable.

## RECOMMENDATIONS:

The registrant should correct the CAS numbers for the [REDACTED]  
[REDACTED]



# DATA PACKAGE BEAN SHEET

Date: 10-Apr-2013

Page 1 of 1

Decision #: 477393

DP #: (410909)

NON PRIA

Parent DP #:

Submission #: 933371

E-Sub #:

## \*\*\* Registration Information \*\*\*

Registration: **66171-7 - SYNERGIZE**

Company: 66171 - PRESERVE INTERNATIONAL

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Emilia Oiguenblik EOIGUENB

Sent Date: 27-Mar-2013

PRIA Due Date: 25-Jun-2013

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (362) FORMULA CHANGE; TECHNICAL;

Ingredients: 043901, Glutaraldehyde(7%)

069175, Alkyl\* dimethyl benzyl ammonium chloride \*(67%C12, 25%C14, 7%C16, 1%C18)(26%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 10-Apr-2013

Due Back: \_\_\_\_\_

DP Ingredient: 069175, Alkyl\* dimethyl benzyl ammonium chloride \*(67%C12, 25%C14, 7%C16, 1%C18)

043901, Glutaraldehyde

DP Title: CSF Amendment

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: \_\_\_\_\_

Assigned To

Date In

Date Out

Organization: AD / PSB

Last Possible Science Due Date: 11-May-2013

Team Name: CTT

Reviewer Name:

Salvador

4/10/13

04/10/13  
04/10/13

Science Due Date: \_\_\_\_\_

Sub Data Package Due Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

## \*\*\* Studies Sent for Review \*\*\*

No Studies

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

Karen- Chemistry, Registrant has submitted a CSF to be reviewed.



United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

**Applicant's Name and Address**

Preserve International  
PO Box 17003  
Reno, NV 89511

**EPA File Symbol/Registration Number**

66171-7

**Product Name**

Synergize

**Date of Confidential Statement of Formula (EPA Form 8570-4)**

3/21/13

As an authorized representative of the applicant for registration of the product identified above, I certify that:

**(1) This product contains the following active ingredient(s):**

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride

Glutaraldehyde

**(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.**



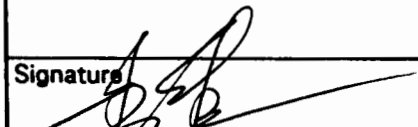
**(3) Indicate by checking (A) or (B) below which paragraph applies:**

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

**(4) The following active ingredients in this product qualify for the formulator's exemption.****Source**

Active Ingredient	Product Name	Registration Number
Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride		
Glutaraldehyde		
	<b>Name and Title</b> Gary E. Gaumer	<b>Date</b> 3/21/13

EPA Form 8570-27 (Rev. 8-95)

★ U.S. GPO: 1996-368-620/20413

White - EPA copy  
Yellow - Applicant copy

Gary E. Gaumer  
Preserve International  
P.O. Box 17003  
Reno, NV 89511

APR 24 2012

SUBJECT: Synergize  
EPA Registration Number: 66171-7  
Application Date: March 21  
Receipt Date: March 27, 2012

Dear Mr. Gaumer:

This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

- To add the Alternate brand name Synergize NP-NF.

Based on a review of the submitted information, this notification is acceptable. Your proposed change will be made part of the record for this file.

#### **General Comments**

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)



United States  
Environmental Protection Agency  
Washington, DC 20460

Registration  
Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 66171-7	2. EPA Product Manager Ms. Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Synergize	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Preserve International PO Box 17003 Reno, NV 89511  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)  
Application for accelerated review as per PR Notice 98-10 Section V(3), Minor Formulation Change

## Section - III

1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 275g,250g,55g,30g,15g,5g,4x1g		5. Location of Label Directions <input checked="" type="checkbox"/> On Label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled		<input checked="" type="checkbox"/> Other Sleeve			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Gary Gaumer		Title President	
		Telephone No. (Include Area Code) 775-853-9776	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) 
2. Signature 		3. Title President	
4. Typed Name Gary Gaumer		5. Date March 21, 2013	



✓ **World Headquarters** P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607  
**Tennessee Operation** 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446  
**California Operation** 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

March 21, 2013

Ms. Velma Noble  
Office of Pesticides Programs (7504C)  
United States Environmental Protection Agency (NOTIFICATION)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Dear Ms. Noble:

Attached to this cover are the documents to support Preserve International's desire to register, via notification, an additional alternate formula for our product Synergize, EPA registration number 66171-7. The Alternate formula identifier for this formula is: Synergize-NP-NF.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,  
Preserve International

Gary E. Gaumer  
President



✓ **World Headquarters** P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607  
**Tennessee Operation** 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446  
**California Operation** 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

January 30, 2013

Ms. Velma Noble  
Office of Pesticides Programs (7504C)  
United States Environmental Protection Agency (AMEND)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Re: Synergize, EPA Registration Number 66171-7

Dear Ms. Noble:

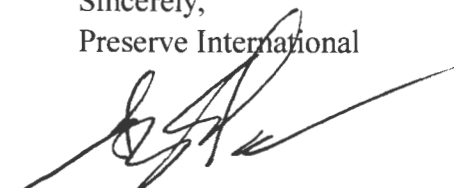
Preserve International hereby submits this amendment to revise the fogging directions for hatchery rooms, incubators and hatchers, and poultry houses and livestock buildings for our product, Synergize, EPA registration number 66171-7.

Included in this submission are the following:

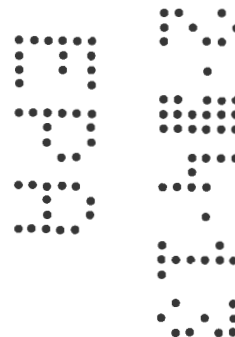
- 1) Application For Pesticide, EPA Form 8570-1
- 2) Five separate printouts documenting the appropriate re-entry times for the various air exchanges listed on the proposed label. These reports are prints developed using the spreadsheet provided by Mr. Timothy Dole, Industrial Hygienist, Antimicrobials Division.
- 3) Five copies of the proposed label.

We thank you for your help in this process.

Sincerely,  
Preserve International



Gary E. Gaumer  
President





U States  
Environmental Protection Agency  
Washington, DC 20460

☐  
☒  
☐

stration  
Amendment  
Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number  
66171-72. EPA Product Manager  
Ms. Velma Noble

3. Proposed Classification

4. Company/Product (Name)  
SynergizePM#  
31
☒ None ☐ Restricted

5. Name and Address of Applicant (Include ZIP Code)

Preserve International  
PO Box 17003  
Reno, NV 89511

☐ Check if this is a new address

6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. \_\_\_\_\_

Product Name \_\_\_\_\_

## Section - II

☒ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated \_\_\_\_\_

☐ Notification - Explain below.

☐ Final printed labels in response to  
Agency letter dated \_\_\_\_\_

☐ "Me Too" Application.

☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Revision of fogging directions for hatchery rooms, incubators and hatchers, and poultry houses and livestock buildings.

## Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging

☐ Yes  
☐ No

Unit Packaging

☐ Yes  
☐ No

Water Soluble Packaging

☐ Yes  
☐ No

2. Type of Container

☐ Metal  
☐ Plastic  
☐ Glass  
☐ Paper  
☐ Other (Specify) \_\_\_\_\_

\* Certification must be submitted

If "Yes"  
Unit Packaging wgt.No. per  
containerIf "Yes"  
Package wgtNo. per  
container

3. Location of Net Contents Information

☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions

☐ On Label  
☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product

☐ Lithograph  
☐ Paper glued  
☐ Stenciled

☐ Other \_\_\_\_\_

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name  
Gary GaumerTitle  
PresidentTelephone No. (Include Area Code)  
775-853-9778

## Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.  
I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or  
both under applicable law.

6. Date Application  
Received  
(Stamp)

2. Signature

3. Title

President

4. Typed Name

5. Date

January 30, 2013

## Glutaraldehyde Air Concentrations for Hatchery Fogging

### Application Parameters

Amount Ai in Product  
 Dilution Rate (1 in X)  
 Product Concentration in Diluted Solution  
 Nozzle Flow Rate  
 Amount of Product Applied per Nozzle  
 Amount Ai Applied per Nozzle (Assuming 128 liquid ounces per gallon and 8.35 lb gallon)  
 Amount Ai Applied per Nozzle (Assuming 454 gm per pound and 1000 mg per gram)  
 Volume Treated per Nozzle  
 Air Changes per Hour  
 Room Volume (Assuming 28.3 liters/ft<sup>3</sup> and 1000 liters/m<sup>3</sup>)  
 Ventilation Rate

7 percent  
 42  
 2.33 percent  
 1.14 ounces/minute  
 0.0265 liquid ounces per minute  
 0.0001211 lb  
 55.0 mg  
 3000 ft<sup>3</sup>  
 84.9 m<sup>3</sup>  
 11.3 m<sup>3</sup>

### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-QT/V})$$

### Rate of Decrease Formula

$$C = C@ \text{ Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

Where:

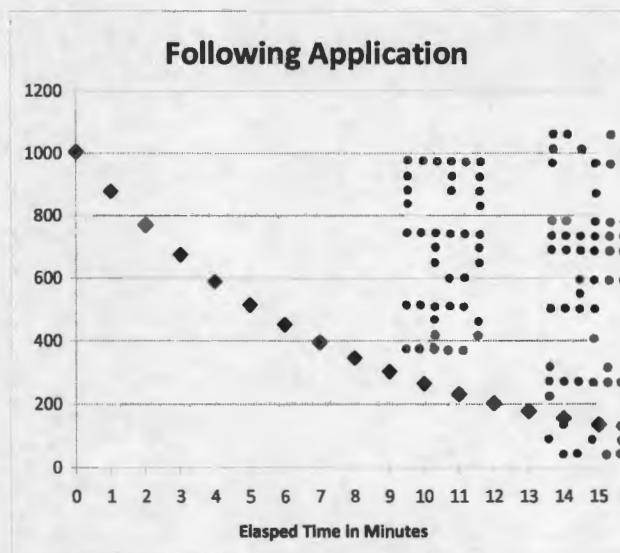
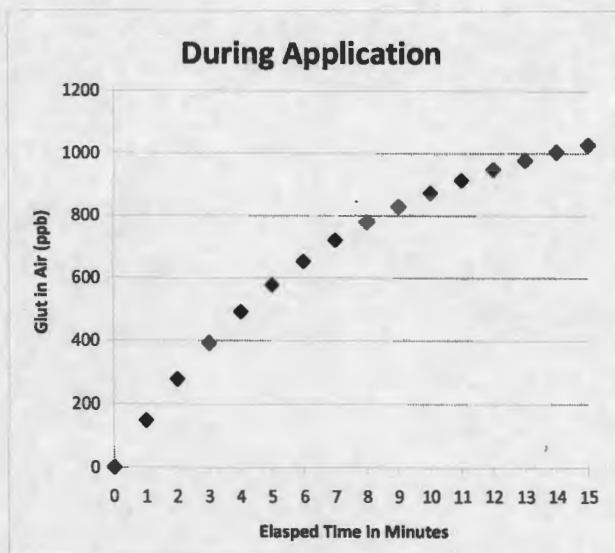
Glutaraldehyde air concentration (C) mg/m<sup>3</sup>  
 Generation Rate (GA) 55.0 mg/min  
 Ventilation Rate (Q) 11.3 M<sup>3</sup>/min  
 Room Volume (V) 84.9 M<sup>3</sup>  
 Elapsed Time (T) Minutes

### Increase During Application

Time	GA/Q	QT/V	e <sup>-QT/V</sup>	C (mg/m <sup>3</sup> )	C (ppb)
0	4.855	0.00	1.000	0	0
1	4.855	0.13	0.875	0.61	148
2	4.855	0.27	0.766	1.14	278
3	4.855	0.40	0.670	1.60	391
4	4.855	0.53	0.587	2.01	491
5	4.855	0.67	0.513	2.36	578
6	4.855	0.80	0.449	2.67	654
7	4.855	0.93	0.393	2.95	720
8	4.855	1.07	0.344	3.18	779
9	4.855	1.20	0.301	3.39	830
10	4.855	1.33	0.264	3.58	874
11	4.855	1.47	0.231	3.74	913
12	4.855	1.60	0.202	3.87	947
13	4.855	1.73	0.177	4.00	977
14	4.855	1.87	0.155	4.10	1004
15	4.855	2.00	0.135	4.20	1026

### Decline following Application

Time (Min)	C (ppb)
0	1004
1	878
2	769
3	673
4	589
5	515
6	451
7	395
8	345
9	302.2
10	264.4
11	231.4
12	202.5
13	177.3
14	155.1
15	135.8





## Glutaraldehyde Air Concentrations for Hatchery Fogging

### Application Parameters

Amount Ai in Product  
 Dilution Rate (1 in X)  
 Product Concentration in Diluted Solution  
 Nozzle Flow Rate  
 Amount of Product Applied per Nozzle  
 Amount Ai Applied per Nozzle (Assuming 128 liquid ounces per gallon and 8.35 lb gallon)  
 Amount Ai Applied per Nozzle (Assuming 454 gm per pound and 1000 mg per gram)  
 Volume Treated per Nozzle  
 Air Changes per Hour  
 Room Volume (Assuming 28.3 liters/ft<sup>3</sup> and 1000 liters/m<sup>3</sup>)  
 Ventilation Rate

7 percent  
 42  
 2.33 percent  
 1.14 ounces/minute  
 0.0265 liquid ounces per minute  
 0.0001211 lb  
 55.0 mg  
 3000 ft<sup>3</sup>  
 84.9 m<sup>3</sup>  
 17.0 m<sup>3</sup>

### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-QT/V})$$

Where:

Glutaraldehyde air concentration (C) mg/m<sup>3</sup>  
 Generation Rate (GA) 55.0 mg/min  
 Ventilation Rate (Q) 17.0 M<sup>3</sup>/min  
 Room Volume (V) 84.9 M<sup>3</sup>  
 Elapsed Time (T) Minutes

### Rate of Decrease Formula

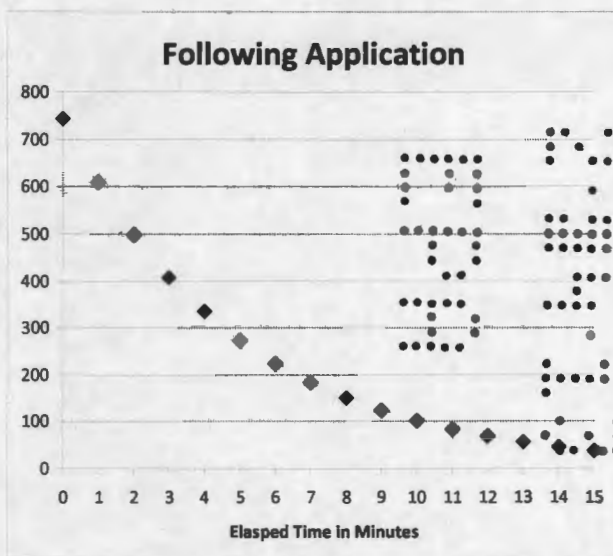
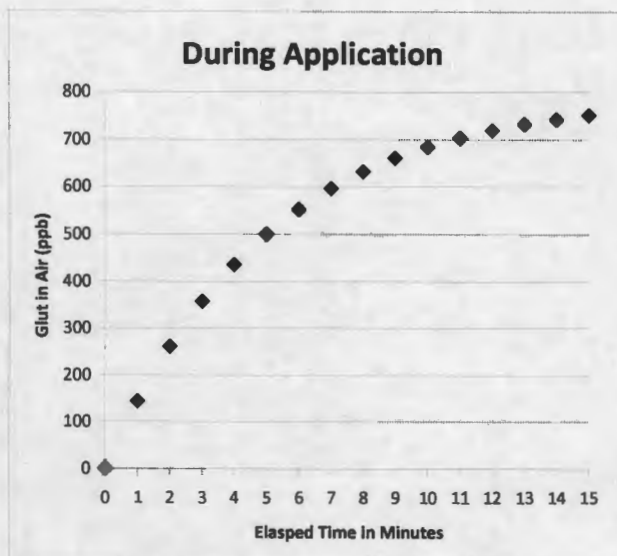
$$C = C@ \text{Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

### Increase During Application

Time	GA/Q	QT/V	e <sup>-QT/V</sup>	C (mg/m <sup>3</sup> )	C (ppb)
0	3.237	0.00	1.000	0	0
1	3.237	0.20	0.819	0.59	143
2	3.237	0.40	0.670	1.07	261
3	3.237	0.60	0.549	1.46	357
4	3.237	0.80	0.449	1.78	436
5	3.237	1.00	0.368	2.05	500
6	3.237	1.20	0.301	2.26	553
7	3.237	1.40	0.247	2.44	596
8	3.237	1.60	0.202	2.58	632
9	3.237	1.80	0.165	2.70	661
10	3.237	2.00	0.135	2.80	684
11	3.237	2.20	0.111	2.88	704
12	3.237	2.40	0.091	2.94	720
13	3.237	2.60	0.074	3.00	733
14	3.237	2.80	0.061	3.04	743
15	3.237	3.00	0.050	3.08	752

### Decline following Application

Time (Min)	C (ppb)
0	743
1	609
2	498
3	408
4	334
5	273
6	224
7	183
8	150
9	122.8
10	100.5
11	82.3
12	67.4
13	55.2
14	45.2
15	37.0



## Glutaraldehyde Air Concentrations for Hatchery Fogging

### Application Parameters

Amount Ai In Product	7 percent
Dilution Rate (1 in X)	42
Product Concentration in Diluted Solution	2.33 percent
Nozzle Flow Rate	1.14 ounces/minute
Amount of Product Applied per Nozzle	0.0265 liquid ounces per minute
Amount Ai Applied per Nozzle (Assuming 128 liquid ounces per gallon and 8.35 lb gallon)	0.0001211 lb
Amount Ai Applied per Nozzle (Assuming 454 gm per pound and 1000 mg per gram)	55.0 mg
Volume Treated per Nozzle	3000 ft <sup>3</sup>
Air Changes per Hour	84.9 m <sup>3</sup>
Room Volume (Assuming 28.3 liters/ft <sup>3</sup> and 1000 liters/m <sup>3</sup> )	22.6 m <sup>3</sup>
Ventilation Rate	

### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-Qt/V})$$

### Rate of Decrease Formula

$$C = C@ \text{ Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

Where:

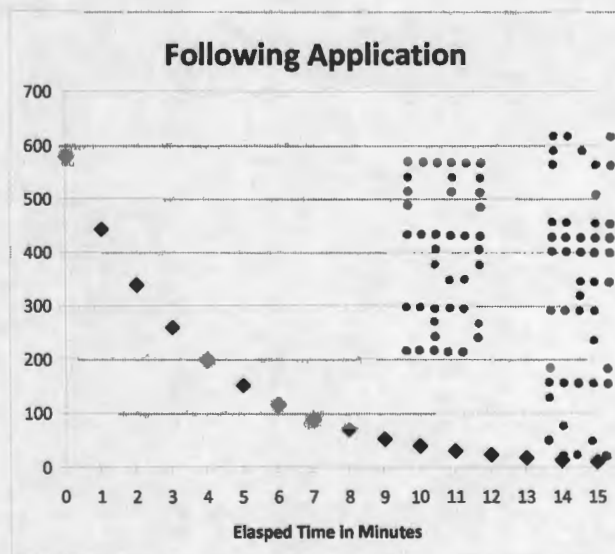
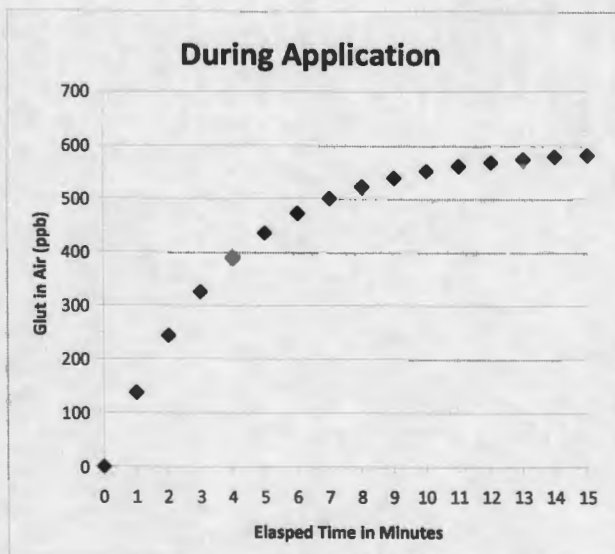
Glutaraldehyde air concentration (C)	mg/m <sup>3</sup>
Generation Rate (GA)	55.0 mg/min
Ventilation Rate (Q)	22.6 M <sup>3</sup> /min
Room Volume (V)	84.9 M <sup>3</sup>
Elapsed Time (T)	Minutes

### Increase During Application

Time	GA/Q	QT/V	$e^{-QT/V}$	C (mg/m <sup>3</sup> )	C (ppb)
0	2.428	0.00	1.000	0	0
1	2.428	0.27	0.766	0.57	139
2	2.428	0.53	0.587	1.00	245
3	2.428	0.80	0.449	1.34	327
4	2.428	1.07	0.344	1.59	389
5	2.428	1.33	0.264	1.79	437
6	2.428	1.60	0.202	1.94	474
7	2.428	1.87	0.155	2.05	502
8	2.428	2.13	0.118	2.14	523
9	2.428	2.40	0.091	2.21	540
10	2.428	2.67	0.070	2.26	552
11	2.428	2.93	0.053	2.30	562
12	2.428	3.20	0.041	2.33	569
13	2.428	3.47	0.031	2.35	575
14	2.428	3.73	0.024	2.37	579
15	2.428	4.00	0.018	2.38	583

### Decline following Application

Time (Min)	C (ppb)
0	579
1	444
2	340
3	260
4	199
5	153
6	117
7	90
8	69
9	52.5
10	40.2
11	30.8
12	23.6
13	18.1
14	13.8
15	10.6



## Glutaraldehyde Air Concentrations for Hatchery Fogging

### Application Parameters

Amount Ai in Product	7 percent
Dilution Rate (1 in X)	42
Product Concentration in Diluted Solution	2.33 percent
Nozzle Flow Rate	1.14 ounces/minute
Amount of Product Applied per Nozzle	0.0265 liquid ounces per minute
Amount Ai Applied per Nozzle (Assuming 128 liquid ounces per gallon and 8.35 lb gallon)	0.0001211 lb
Amount Ai Applied per Nozzle (Assuming 454 gm per pound and 1000 mg per gram)	55.0 mg
Volume Treated per Nozzle	3000 ft <sup>3</sup>
Air Changes per Hour	84.9 m <sup>3</sup>
Room Volume (Assuming 28.3 liters/ft <sup>3</sup> and 1000 liters/m <sup>3</sup> )	28.3 m <sup>3</sup>
Ventilation Rate	

### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-QT/V})$$

### Rate of Decrease Formula

$$C = C@ \text{ Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

Where:

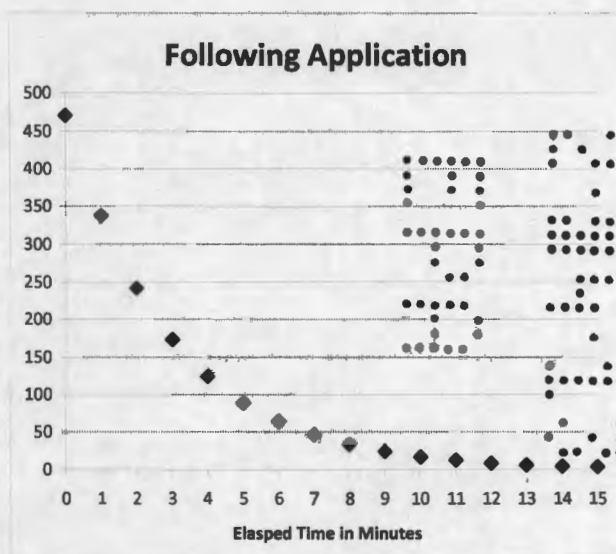
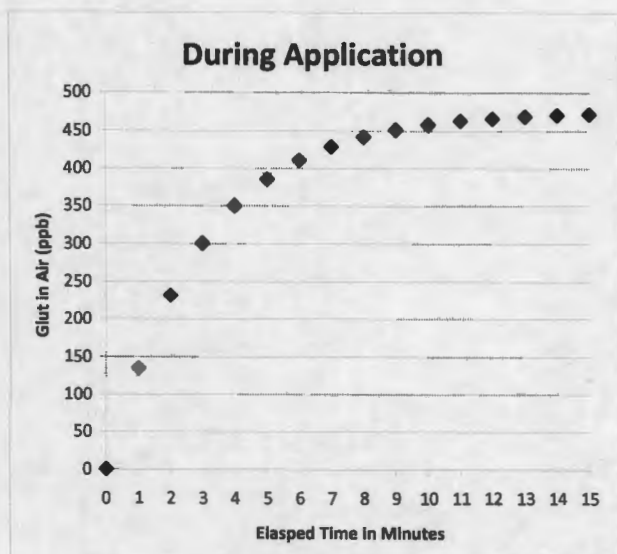
Glutaraldehyde air concentration (C)	mg/m <sup>3</sup>
Generation Rate (GA)	55.0 mg/min
Ventilation Rate (Q)	28.3 M <sup>3</sup> /min
Room Volume (V)	84.9 M <sup>3</sup>
Elapsed Time (T)	Minutes

### Increase During Application

Time	GA/Q	QT/V	$e^{-QT/V}$	C (mg/m <sup>3</sup> )	C (ppb)
0	1.942	0.00	1.000	0	0
1	1.942	0.33	0.717	0.55	135
2	1.942	0.67	0.513	0.94	231
3	1.942	1.00	0.368	1.23	300
4	1.942	1.33	0.264	1.43	350
5	1.942	1.67	0.189	1.58	385
6	1.942	2.00	0.135	1.68	411
7	1.942	2.33	0.097	1.75	429
8	1.942	2.67	0.070	1.81	442
9	1.942	3.00	0.050	1.85	451
10	1.942	3.33	0.036	1.87	458
11	1.942	3.67	0.026	1.89	463
12	1.942	4.00	0.018	1.91	466
13	1.942	4.33	0.013	1.92	469
14	1.942	4.67	0.009	1.92	470
15	1.942	5.00	0.007	1.93	472

### Decline following Application

Time (Min)	C (ppb)
0	470
1	337
2	241
3	173
4	124
5	89
6	64
7	46
8	33
9	23.4
10	16.8
11	12.0
12	8.6
13	6.2
14	4.4
15	3.2



## Glutaraldehyde Air Concentrations for Hatchery Fogging

### Application Parameters

Amount Ai in Product  
 Dilution Rate (1 in X)  
 Product Concentration in Diluted Solution  
 Nozzle Flow Rate  
 Amount of Product Applied per Nozzle  
 Amount Ai Applied per Nozzle (Assuming 128 liquid ounces per gallon and 8.35 lb gallon)  
 Amount Ai Applied per Nozzle (Assuming 454 gm per pound and 1000 mg per gram)  
 Volume Treated per Nozzle  
 Air Changes per Hour  
 Room Volume (Assuming 28.3 liters/ft<sup>3</sup> and 1000 liters/m<sup>3</sup>)  
 Ventilation Rate

7 percent  
 42  
 2.33 percent  
 1.14 ounces/minute  
 0.0265 liquid ounces per minute  
 0.0001211 lb  
 55.0 mg  
 3000 ft<sup>3</sup>  
 84.9 m<sup>3</sup>  
 34.0 m<sup>3</sup>

### Rate of Increase Formula

$$C = (GA/Q) * (1 - e^{-QT/V})$$

### Rate of Decrease Formula

$$C = C@ \text{ Time Zero} * 0.5^{(T/0.693 * Q/V)}$$

Where:

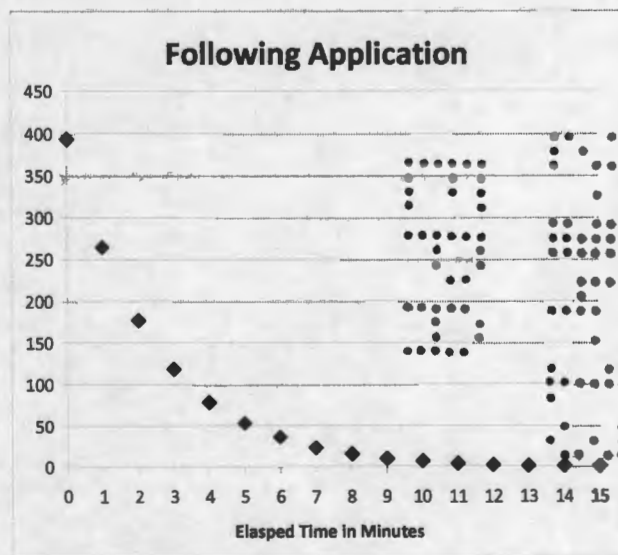
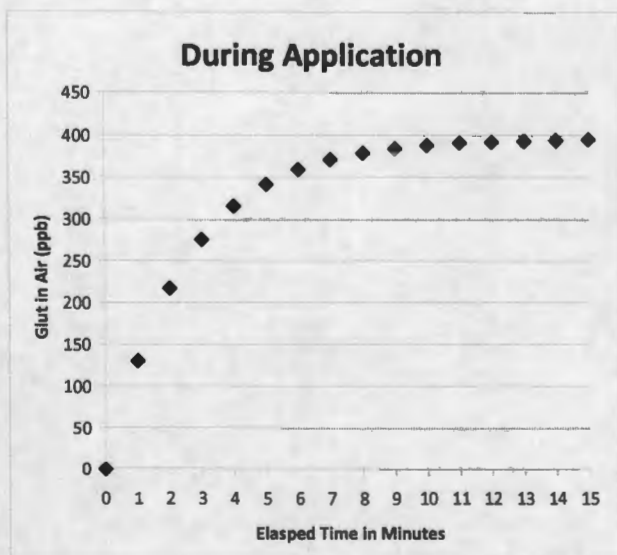
Glutaraldehyde air concentration (C) mg/m<sup>3</sup>  
 Generation Rate (GA) 55.0 mg/min  
 Ventilation Rate (Q) 34.0 M<sup>3</sup>/min  
 Room Volume (V) 84.9 M<sup>3</sup>  
 Elapsed Time (T) Minutes

### Increase During Application

Time	GA/Q	QT/V	e <sup>-QT/V</sup>	C (mg/m <sup>3</sup> )	C (ppb)
0	1.618	0.00	1.000	0	0
1	1.618	0.40	0.670	0.53	130
2	1.618	0.80	0.449	0.89	218
3	1.618	1.20	0.301	1.13	277
4	1.618	1.60	0.202	1.29	316
5	1.618	2.00	0.135	1.40	342
6	1.618	2.40	0.091	1.47	360
7	1.618	2.80	0.061	1.52	372
8	1.618	3.20	0.041	1.55	380
9	1.618	3.60	0.027	1.57	385
10	1.618	4.00	0.018	1.59	388
11	1.618	4.40	0.012	1.60	391
12	1.618	4.80	0.008	1.61	392
13	1.618	5.20	0.006	1.61	394
14	1.618	5.60	0.004	1.61	394
15	1.618	6.00	0.002	1.61	395

### Decline following Application

Time (Min)	C (ppb)
0	394
1	264
2	177
3	119
4	80
5	53
6	36
7	24
8	16
9	10.8
10	7.2
11	4.8
12	3.2
13	2.2
14	1.5
15	1.0



## DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleanser. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO<sub>3</sub>) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

## DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on food, food or litter.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

## USE DIRECTIONS:

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to pre-cleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

**BOOT/SHOE WASH:** To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution must be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

**VEHICLES:** To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

## DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARN, RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.

Manufactured by:

**PRESERVE**  
INTERNATIONAL

Reno, NV 89511 • (800) 995-1607 • [www.preserveinternational.com](http://www.preserveinternational.com)

Page 1 of 2

# SYNERGIZE™ CLEANER-DISINFECTANT

STAPHYLOCIDAL • PSEUDOMONACIDAL

• SALMONELLACIDAL • VIRUCIDAL •

• PARVOCIDAL • FUNGICIDAL

ASPERGILLOCIDAL

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, Veterinary Practice, Animal Care, and Animal Laboratory.

## Active Ingredients:

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride.....	26.00%
Glutaraldehyde.....	7.00%
Inert Ingredients.....	67.00%
TOTAL.....	100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

EPA Reg. No.

EPA Est.

Patent Number:

66171-7

66171-TN-001, 66171-CA-001

5,891,922

Batch No: \_\_\_\_\_

Net Contents: \_\_\_\_\_

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

## PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

## PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. (For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

**General:** Consult Federal, State or local disposal authorities for approved procedures.

## PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

## DANGER

**KEEP OUT OF REACH OF CHILDREN.** Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS:** This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## FIRST AID

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing; call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

**HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.



# SYNERGIZE

## HATCHERY ROOMS, INCUBATORS AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING:

All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices. Fogging is not used as a sanitizing treatment. Close room off so fog is confined to room to be treated. Hatchery ventilation systems must remain on during fogging. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus.

**A) HATCHERY ROOMS:** Vacate all personnel from hatchery room to be fogged. Close room off so fog is confined to the hatchery room to be treated. Prepare a stock solution of one (1) part Synergize to forty-two (42) parts water (3 fluid ounces Synergize to 125 fluid ounces water). Fog this solution at a rate of 3.8 ounces per minute per 10,000 cubic feet for the fogging times specified in the chart below. Contact your Preserve International representative to determine the recommended fogging schedule. Do not allow people to breathe or contact the fog. When fogging Synergize, re-entry intervals (REI) and personnel protection equipment (PPE) are determined by the following hatchery room air exchange rates:

Hatchery Room ACH	Fogging Time	Re-entry Intervals (REI)	PPE Required
8 Air Exchanges Per Hour	5 Minutes	25 Minutes	No PPE Required
12 Air Exchanges Per Hour	7.5 Minutes	15 Minutes	No PPE Required
16 Air Exchanges Per Hour	10 Minutes	10 Minutes	No PPE Required
20 Air Exchanges Per Hour	12.5 Minutes	10 Minutes	No PPE Required
24 Air Exchanges Per Hour	15 Minutes	10 Minutes	No PPE Required

Under no circumstances must the hatchery room be entered by unprotected persons before the listed re-entry intervals. If the hatchery room must be entered, before the listed re-entry intervals, then the individuals entering the room must wear a long sleeve shirt and pants and an approved NIOSH/MSHA full facepiece respirator, such as the 3M 6700-6900 series, with an organic vapor cartridge, such as the 3M 6001, and a particulate filter, such as the 3M 5N11 & 3M 501 filter retainer.

## B) INCUBATORS AND HATCHERS:

Only for treatment of setters and hatchers after poultry/chicks/eggs have been removed. Not for treatment of hatchers which contain chicks/eggs. Prepare a stock solution of one (1) part Synergize to forty-two (42) parts water. Fog three (3) ounces per 100 cubic feet of solution into setters and hatchers immediately after transfer. Repeat daily. Discontinue hatchery treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has been exhausted. To do permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 solution of Synergize. If this is done, fog for 30 - 90 seconds once per hour or once every 12 hours.

## C) POULTRY HOUSES AND LIVESTOCK BUILDINGS:

After the house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, ratite facilities, calf pens and vehicles", double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as possible. Prepare a stock solution of one (1) part Synergize to four (4) parts water (25 fluid ounces Synergize to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, for 125 fluid ounces for each 1000 cubic yards. The Fogger itself is placed just inside the door of the building to be treated, or the nozzle of the fogger is inserted through a suitable opening in the door or building. The opening must be large enough to accommodate the nozzle. After fogging, the building must be kept closed for twenty-four (24) hours. After twenty-four (24) hours, the fog must have settled and the house can now be opened and aired. The house must be opened for a minimum of twenty-four (24) hours before it is repopulated with poultry or livestock.

**NOTE FOR POULTRY HOUSES AND LIVESTOCK BUILDINGS:** The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances must a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self-contained respirator approved by NIOSH/MSHA, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they must be washed with detergent and water before use for poultry or livestock.

## AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:

This product may only be used in industrial air washers and air washer systems which have mist-eliminating components.

SYNERGIZE must be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as a basin area. Addition may be made intermittently (Slug Dose) or continuously. Badly fouled systems can be shock treated with SYNERGIZE. Under these conditions, blowdown must be discontinued for up to 24 hours.

SYNERGIZE can be used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

### Intermittent (Slug Dose) Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

### Continuous Feed Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

**VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/ANIMAL LABORATORY/ANIMAL LIFE SCIENCE LABORATORY/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOO/PET SHOP/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREEDING FACILITIES/BREEDING AND GROOMING ESTABLISHMENT/TACK SHOPS DISINFECTION DIRECTIONS:** For cleaning and disinfecting the following hard, non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stalls and catteries. Remove all animals (and) feeds from areas to be treated, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with detergent and rinse with water. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used in removing litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers, and other equipment which dispenses food or water with soap or detergent, and rinse with potable water before reuse. At 1/2 ounce per gallon of water, in the presence of 1000 ppm of hardness and 5% organic load for a 10-minute contact time, Synergize was found to be effective against Canine Parvovirus.

Staphylococcus aureus A.T.C.C. 6538  
Pseudomonas aeruginosa A.T.C.C. 15442  
Salmonella enterica A.T.C.C. 10708  
Aspergillus fumigatus A.T.C.C. 36607  
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)  
Salmonella Enteritidis

Avian Influenza (H3N2)\*  
Escherichia Coli F18  
Porcine circovirus Type 2\*  
Canine parvovirus A.T.C.C. VR-2016\*  
Salmonella Choleraesuis

Manufactured by:  
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Page 2 of 2

## DOT SHIPPING NAME

UN3264, Corrosive Liquid, Acidic, Inorganic,  
n.o.s. (Phosphoric Acid), 8, PG III

1/29/2013

# Material Sent for Data Extraction

Reg # 66171-7

Description: \_\_\_\_\_

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated \_\_\_\_\_

☒ Notification Dated \_\_\_\_\_

☐ New CSF(s) Dated \_\_\_\_\_

☐ Other: \_\_\_\_\_

☐ Decision #: \_\_\_\_\_

☐ Other Action/Comments: \_\_\_\_\_

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Dm Team 21

Phone: 203 308 8032 Division: AD

Date: 6/4/12

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



United States  
Environmental Protection  
Agency

**Office of Pesticide Programs**

Gary E. Gaumer,  
Preserve International,  
P.O. Box 17003,  
Reno, NV 89511

JUN 13 2012

Subject: Synergize  
EPA Registration No.: 66171-7  
Notification Date: May 2, 2012  
EPA Receipt Date: May 14, 2012  
Submission #: 916796

Dear Mr. Gaumer,

This letter acknowledges receipt of your notification submitted under the provision of FIFRA section 3(c)9 and PR Notice 98-10.

**Proposed notification request for alternative brand name:**

- **Alternative brand name:** "Synergize Cool".

**General Comments**

Based on a review of the submitted materials your notification of a request for an alternative brand name for your product, "Synergy Cool", is acceptable. A copy of this letter has been placed in your file.

Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233 or Jamil Mixon at (703) 308-8032.

Sincerely,

A handwritten signature in black ink, appearing to read "Velma Noble".

Velma Noble  
Product Manager -31  
Regulatory Management Branch  
Antimicrobials Division (7510P)



**RISK ASSIGNMENT FORM**  
Antimicrobial Division/Regulatory Management Branch I

<b>A</b>	Completed by Product Manager						
PRODUCT REVIEWER: <i>Cletis</i>					RMBI <u>TEAM 31</u>		
Type of Action: <i>Not. Grant</i>					EPA File Symbol/Reg No. <i>66171-7</i>		
Decision No. <i>465217</i>		Submission No. <i>916796</i>		Fee for Service Action Code:			
FQPA Action Code: <i>332</i>		Non-FQPA Action Code:		PRIA FEE AMOUNT:			
		MONTH	DAY	YEAR			
APPLICATION DATE		<i>5</i>	<i>2</i>	<i>2012</i>			
EPA PIN DATE		<i>5</i>	<i>14</i>	<i>2012</i>			
DATE PM RECEIVED FROM FRONT END				<i>2012</i>			
DATE SENT TO SCIENCE							
DATE RECEIVED FROM SCIENCE							
DATE DUE TO PM		<i>6</i>	<i>14</i>				
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure/Residue
<i>Not. Grant - Give to Cletis</i>							
ATTACHMENTS:   -LABELING                      e-CSF(S)                      e-DATA                      e-OTHERS							
<b>B</b>	For Arctic Slope Contract Only						
	Contract No.: 0052		ARCTIC SLOPE/MANAGER				
	Final Task: Signature _____ (Total hrs)						
<b>C</b>	Reviewer Comments:						
DATE FEE PAID:				RESPONSE CODE:		RESPONSE DATE:	

# Receipt for Section 3

S: 816796

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Notification

Company: 66171 PRESERVE INTERNATIONAL V

Risk Manager: Antimicrobials Division, Risk Management Team 31

Product #: 66171-7 Product Name: SYNERGIZE

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 02-May-2012 id

OPP Rec'd Date: 14-May-2012 id

Front End Date: 14-May-2012 id

Risk Manager Send Date: 14-May-2012 id

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Notification Brand Name

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Other

Notification for Brand

View/Edit



Office of Gary E. Gaumer P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 853-9212 • email: gegaumer@preserveinc.com

May 2, 2012

Ms. Velma Noble  
Office of Pesticides Programs (7504C)  
United States Environmental Protection Agency (NOTIFY)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Dear Ms. Noble:

Preserve International hereby submits this notification for Alternate Brand Name for Synergize, EPA registration number 66171-7.

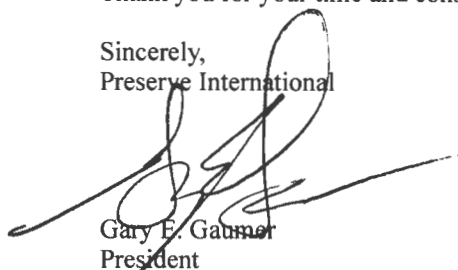
Alternate Brand Name requested: Synergize Cool

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

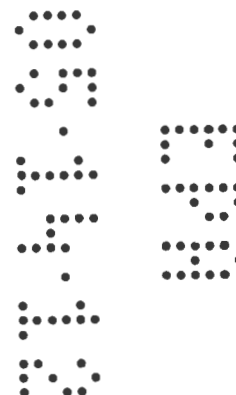
If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,  
Preserve International



Gary E. Gaumer  
President



Gary E. Gaumer  
Preserve International  
P.O. Box 17003  
Reno, NV 89511

MAY 18 2012

SUBJECT: Synergize  
EPA Registration Number: 66171-7  
Application Date: April 18, 2012  
Receipt Date: April 23, 2012

Dear Mr. Gaumer:

This letter acknowledges receipt of the notification identified above submitted under the provisions of section 3 (c) 9 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended and PR Notice 98-10 and 40 CFR 152.46.

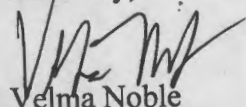
- To add the Alternate brand name Synergize Cool.

Based on a review of the submitted information, this notification is acceptable. Your proposed change will be made part of the record for this file.

#### General Comments

Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Gary E. Gaumer  
Preserve International  
P.O. Box 17003  
Reno, NV 89511

MAY 18 2012

SUBJECT: Synergize  
EPA Registration Number: 66171-7  
Application Date: August 31, 2011  
Receipt Date: September 7, 2011

Dear Mr. Gaumer:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(C)(7)(A) is acceptable with the condition below.

- On page 2 of the proposed label in the section B) INCUBATORS AND HATCHERS, the statement "disperse the sanitizing solution as a fog" must be revised as the fogging use is only an adjunct treatment (Agency letters of 12/30/2010 and 7/23/2010). Revise this statement to read "...disperse the solution as a fog..." by deleting the word "sanitizing".

**Efficacy Data**

The following study has been reviewed in support of this product.. The review of this data is attached.

Data Requirement	Means of Support	Status
Salmonella enteric subsp. enterica serovar enteritidis (ATCC 13076)	Submitted study, MRID 485944-01	Acceptable, 1/2 ounce product per 1 gallon of water, 5% soil and 1000 ppm hard water for a 10 minutes contact time

**General Comments**

This letter supersedes the letter dated February 16, 2012.

CONCURRENCES

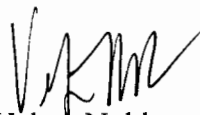
SYMBOL								
SURNAME								
DATE								

Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,

A handwritten signature in black ink, appearing to read 'V. Noble', with a stylized flourish at the end.

Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)



**RISK ASSIGNMENT FORM**  
Antimicrobial Division/Regulatory Management Branch I

<b>A</b>		Completed by Product Manager					
PRODUCT REVIEWER: <i>Em. Lee</i>					RMBI <u>TEAM 31</u>		
Type of Action: <i>CSF Amendment</i>					EPA File Symbol/Reg No. <i>66171-7</i>		
Decision No. <i>477393</i>		Submission No. <i>933371</i>		Fee for Service Action Code:			
FQPA Action Code: <i>362</i>		Non-FQPA Action Code:		PRIA FEE AMOUNT:			
		MONTH	DAY	YEAR			
APPLICATION DATE		<i>3</i>	<i>21</i>	<i>2012</i>			
EPA PIN DATE		<i>3</i>	<i>27</i>	<i>2012</i>			
DATE PM RECEIVED FROM FRONT END				<i>2012</i>			
DATE SENT TO SCIENCE							
DATE RECEIVED FROM SCIENCE							
DATE DUE TO PM		<i>June</i>	<i>25</i>				
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure/Residue
<i>Karen - Chemistry - Registrant has submitted CSF to be reviewed</i>							
ATTACHMENTS: LABELING e-CSF(S) e-DATA e-OTHERS							
<b>B</b>		For Arctic Slope Contract Only					
Contract No.: 0052		ARCTIC SLOPE/MANAGER					
Final Task: Signature _____		(Total hrs) _____					
<b>C</b>		Reviewer Comments:					
DATE FEE PAID:		RESPONSE CODE:		RESPONSE DATE:			

66171-7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

2/16/2012

1/4

Gary E. Gaumer  
Preserve International  
P.O. Box 17003  
Reno, NV 89511

*Similar  
connection  
letter*

FEB 16 2012

SUBJECT: Synergize  
EPA Registration Number: 66171-7  
Application Date: August 31, 2011  
Receipt Date: September 7, 2011

Dear Mr. Gaumer:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(C)(7)(A) is acceptable with the condition below.

- On page 2 of the proposed label in the section B) INCUBATORS AND HATCHERS, the statement "disperse the sanitizing solution as a fog" must be revised as the fogging use is only an adjunct treatment (Agency letters of 12/30/2010 and 7/23/2010). Revise this statement to read "...disperse the solution as a fog..." by deleting the word "sanitizing".

#### Efficacy Data

The following study has been reviewed in support of this product. The review of this data is attached.

Data Requirement	Means of Support	Status
Salmonella enteric subsp. enterica serovar enteritidis (ATCC 13076)	Submitted study, MRID 485944-01	Acceptable, 1/2 ounce product per 1 gallon of water, 5% soil, contact time of 10 minutes

#### General Comments

Hard Water Not Listed;  
Should be 1000ppm; Test Attached.

A stamped copy of the accepted labeling with conditions is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling.

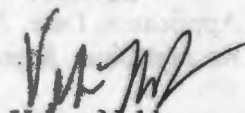
SYMBOL							
SURNAME							
DATE							



Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Attachments: Stamped label and Efficacy review DP Barcode: D394286

<p>Product Name: [illegible] EPA Reg. No.: [illegible] FIFRA Section 3(c)(5) Data: [illegible]</p>	<p>Product Name: [illegible] EPA Reg. No.: [illegible] FIFRA Section 3(c)(5) Data: [illegible]</p>	<p>Product Name: [illegible] EPA Reg. No.: [illegible] FIFRA Section 3(c)(5) Data: [illegible]</p>
--	--	--

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
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#### DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleanser. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO<sub>3</sub>) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

#### DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on food, food or filler.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Laver, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premises, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

#### USE DIRECTIONS:

1) Disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to pre-cleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

**BOOT/SHOE WASH:** To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution must be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

**VEHICLES:** To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

#### DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and rakes used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARN, RATITE FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.

Manufactured by:

**PRESERVE**  
INTERNATIONAL

Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com

Page 1 of 2

# SYNERGIZE

## CLEANER-DISINFECTANT

STAPHYLOCIDAL • PSEUDOMONACIDAL  
• SALMONELLACIDAL • VIRUCIDAL •  
• PARVOCIDAL • FUNGICIDAL  
ASPERGILLOCIDAL

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Laver, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premises, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, Veterinary Practice, Animal Care, and Animal Laboratory.

#### Active Ingredients:

Alkyl (C12 87%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride.....	28.00%
Gluconic acid.....	7.00%
Water.....	65.00%
TOTAL.....	100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.

8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.

9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and trailers.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

EPA Reg. No.  
EPA Est.  
Patent Number:

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

66171-7  
66171-TN-001, 66171-CA-001  
8,891,922

Batch No:

Net Contents:

FEB 16 2002

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No

66171-7

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

#### PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container.

#### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

**General:** Consult Federal, State or local disposal authorities for approved alternative procedures.

## PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

#### DANGER

**KEEP OUT OF REACH OF CHILDREN.** Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/fogging respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, R, P, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS:** This product is toxic to fish aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## FIRST AID

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

**HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

187/11

# SYNERGIZE

## HATCHERY ROOMS, INCUBATORS, AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING:

All surfaces must be cleaned and disinfected prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices. Fogging is not used as a sanitizing treatment. Close room off so fog is confined to room to be treated. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus.

### A) HATCHERY ROOMS:

Remove all animals and feed from premises, vehicles and enclosures. Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in be room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.

### B) INCUBATORS AND HATCHERS:

Only for treatment of setters and hatchers after poultry / chicks / eggs have been removed. Not for treatment of hatchers which contain chicks / eggs. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water. Fog three (3) ounces per 100 cubic feet of this fogging solution into setters and hatchers immediately after transfer. Repeat daily. Discontinue Hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 solution of SYNERGIZE. If this is done, fog for 30-60 seconds once per hour or once every two hours.

### C) POULTRY HOUSES AND LIVESTOCK BUILDINGS:

After the house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, cattle facilities, calf pens and vehicles, double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as possible. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. The fogger itself may be placed just inside the door of the building to be treated, or the nozzle of the fogger may be inserted through a suitable opening in the door or building. The opening must be large enough to accommodate the nozzle. After fogging, the building must be kept closed for twenty-four (24) hours. After twenty-four (24) hours, the fog must have settled and the house can now be opened and aired. The house must be opened for a minimum of twenty-four (24) hours before it is repopulated with poultry or livestock.

**NOTE:** The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances must a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSH, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they must be washed with detergent and water before use for poultry or livestock.

## AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:

This product may only be used in industrial air washers and air washer systems which have mist-eliminating components.

SYNERGIZE must be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as a basin area. Addition may be made intermittently (Slug Dose) or continuously. Badly fouled systems can be shock treated with SYNERGIZE. Under these conditions, blowdown must be discontinued for up to 24 hours.

SYNERGIZE can be used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

### Intermittent (Slug Dose) Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

### Continuous Feed Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

**VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/ANIMAL LABORATORY/ANIMAL LIFE SCIENCE LABORATORY/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREA/PET SHOP/KENNEL/ANIMAL HUSBANDRY/ANIMAL BREEDING FACILITIES/BREEDING AND GROOMING ESTABLISHMENT/TACK SHOPS DISINFECTION DIRECTIONS:** For cleaning and disinfecting the following hard, non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, stalls and trailers. Remove all animals (and) feeds from areas to be treated, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers, and other equipment which dispenses food or water with soap or detergent, and rinse with potable water before reuse. At 1/4 ounce per gallon of water, in the presence of 1000 ppm of hardness and 5% organic load for a 10-minute contact time, this product was found to be effective against Canine Parvovirus.

Staphylococcus aureus A.T.C.C. 6538  
Pseudomonas aeruginosa A.T.C.C. 15442  
Salmonella enterica A.T.C.C. 10706  
Aspergillus fumigatus A.T.C.C. 36607  
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)\*  
Avian Influenza (H5N2)\*  
Escherichia Coli F18  
Porcine circovirus Type 2\*  
Canine parvovirus A.T.C.C. VR-2016\*

Salmonella Choleraesuis  
Salmonella Enteritidis

Manufactured by:  
**PRESERVE**  
INTERNATIONAL  
Reno, NV 89511 • (800) 995-1607 • [www.preserveinternational.com](http://www.preserveinternational.com)  
Page 2 of 2

## DOT SHIPPING NAME

UN3264, Corrosive Liquid, Acidic, inorganic,  
n.o.s. (Phosphoric Acid), 8, PG III

12/7/11

# Antimicrobial Test Laboratories

## Fast, Reliable Antimicrobial Efficacy Testing

Study ID: GLP1077

Client: Preserve International

Protocol Number: P1084

### FINAL STUDY REPORT

#### Important Dates

Study Initiation Date: 28 July 2011  
Experimental Start Date: 29 July 2011  
Experimental End Date: 01 August 2011

Name:	Synergize
Date(s) Received:	12 April 2011
Lot Number(s):	37817 & 37818
Active Ingredient(s):	Glutaraldehyde (ca. 0.03%) Alkyl Dimethyl Benzyl Ammonium Chloride (ca. 0.1%)
Expiration Date(s):	25 MAR 2013 (Lots 37817 & 37818)
Dilution Tested:	1:256 (1 part test substance plus 255 parts diluent)
Storage Conditions:	Room Temperature

#### Test Parameters

Microorganism:	<i>Salmonella enterica</i> subsp. enterica serovar Enteritidis ATCC 13076
Subculture Number:	4
Number of Test Carriers:	10 Carriers/Lot Tested (20 Carriers Total)
Carrier Type:	Stainless steel penicylinder
Contact Time:	10 minutes
Contact Temperature:	22.2°C
Diluent Type:	1010ppm AOAC Hard Water
Organic Soil Load:	5.0% (v/v) sterile equine serum
Culture Volume:	38ml
Volume soil added:	2ml
Carrier Soak Time:	15 minutes
Carrier Dry Time:	38 minutes
Carrier Dry Temperature:	35.4°C
Incubation Temperature:	36±1°C
Incubation Time:	46 Hrs 28 Min.

#### Test Method

The test was conducted according to the attached protocol.



MAY 7 2012

Mr. Gary E. Gaumer  
 President  
 Preserve International  
 P.O. Box 17003  
 Reno, NV 89511

Subject: **Synergize**  
 EPA Registration Number 66171-7  
 Application Dated July 24, 2006  
 EPA Received Date July 28, 2006

Dear Mr. Gaumer:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with the following comments:

**Proposed Amendment:**

- Add additional organism (Porcine corcovirus Type 2 to label)

**Efficacy Review:**

1. The proposed label claims that the product, Synergize, is an effective disinfectant against Porcine corcovirus type 2 on hard, non-porous surfaces in the presence of 1000 ppm hard water and 5% organic soil load for a contact time of 10 minutes at a ½ ounce per gallon dilution. Data provided supports this claim.
2. Make the following changes to the proposed label:
  - a. Under the "Description" section (left panel), change "fiberglass" to read "sealed fiberglass." Fiberglass is a porous surface.
  - b. Under the "Use Directions" section regarding vehicles (left panel), change "course spray" to read "coarse spray."

c. Under the list of microorganisms, change "Avian influenza" read "Avian Influenza virus (H3N2)".

SYMBOL							
SURNAME							
DATE							

- d. Under Active ingredient statement line up the "percentage numbers and total".

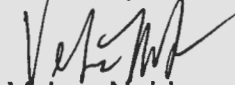
**General Comments:**

**NOTE: This letter supersedes the letter dated February 7, 2007.**

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Enclosure

66171-7

UI ED 1

02/07/2007  
ES ENVIRONMENTAL PROTECT IN AGENCY

1/4

FEB - 7 2007

-Mr. Gary E. Gaumer  
President  
Preserve International  
P. O. Box 17003  
Reno, NV 89511

Subject: **Synergize**  
EPA Registration Number 66171-7  
Your Application Dated: July 24, 2006  
EPA Received Data: July 28, 2006

Dear Mr. Gaumer:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable with the following comments:

**Proposed Labeling:**

Add additional organism (Porcine circovirus type 2 to label)

**Efficacy Review:**

1. The proposed label claims that the product, Synergize, is an effective disinfectant against Porcine circovirus type 2 on hard, non-porous surfaces in the presence of 1000 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1 ounce per gallon dilution. Data provided supports this claim.

The Dilution of 1 ounce per gallon should be 1/2 ounce per gallon. Test Attached.

2. Make the following changes to the proposed label:
  - a. Under the "Description" section ( left panel), change "fiberglass" to read "sealed fiberglass." Fiberglass is a porous surface.
  - b. Under the "Use Directions" section regarding vehicles (left panel), change "course spray " to read "coarse spray."
  - c. Under the list of microorganisms, change "Avian influenza" to read "Avian Influenza virus (H3N2)".

d. Under Active Ingredients, statement line up the "percentage numbers and total".

SYMBOL							
SURNAME							
DATE							

2/4

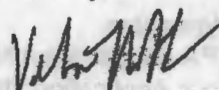
**Other Comments:**

Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

A stamped copy of the label is enclosed for your records.

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224.

Sincerely,



Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

Enclosure:



## DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO<sub>3</sub>) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

## DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premises, Equine Facilities, Veal Barns, Rattle Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

## USE DIRECTIONS:

To disinfect: Clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exterior, phone booths and garbage cans in non-animal areas associated with the site noted below. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to pre-cleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

BOOTS/SHOE WASH: To prevent tracking harmful organisms into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

## DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.

7) Immerse all equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.

8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.

9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARN, RATTLE FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.

Manufactured By:

**PRESERVE INTERNATIONAL**

Zephyr Cove, NV 89448 (209) 664-1607 • www.preserveinternational.com 66171-7

# SYNERGIZE CLEANER-DISINFECTANT

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premises, Equine Facilities, Veal Barns, Rattle Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

Staphylococcus aureus A.T.C.C. 6538

Salmonella choleraesuis A.T.C.C. 10708

Porcine Respiratory & Reproductive Syndrome Virus (PRRS)

Escherichia Coli F18

Pseudomonas aeruginosa A.T.C.C. 15442

Aspergillus fumigatus A.T.C.C. 36007

Avian Influenza

Porcine circovirus Type 2

## ACTIVE INGREDIENTS

Alkyl (C<sub>12</sub> 67%, C<sub>14</sub> 25%, C<sub>16</sub> 7%, C<sub>18</sub> 1%) dimethyl benzyl ammonium chloride 28.00%

Glutaraldehyde .....7.00%

INERT INGREDIENTS .....97.00%

TOTAL .....100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

## SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

## See First Aid statement and additional precautions on side panel STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

## PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

## CONTAINER DISPOSAL:

Plastic: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

## PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

EPA Registration No.: 66171-7

EPA Establishment No.: 66171-7

66171-CA-001

Patent Number: 5,891,922

with COMMENTS

EPA Letter Dated

FEB - 7 2007

## NFPA HAZARD CLASSIFICATION

HEALTH	FLAME	REACTIVITY	SPECIAL HAZARDS
3	1	1	See the Federal Insecticide, Fungicide, and Rodenticide Act for the pesticide.

Classified under EPA Reg. No.

- 7) Immerse all hatters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN POULTRY COOPS:

- 1) Remove all poultry and feed from the premises, troughs, coops and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

Prior to fogging settlers or hatcheries, food products and packaging must be removed from the room or carefully protected. After cleaning, fog desired areas using one quart per 1000 cubic feet of room area with a product solution containing 0.25 to 1 ounce per gallon water. Vaseal all areas of personnel and poultry and feeds for a minimum of 2 hours after fogging. All food contact surfaces, including feed troughs, automatic feeders, and fountains must be disinfected followed by treatment with soap and water or detergent and rinsed with potable water before reuse.

\*NOTE: The fog generated is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone within two hours of the actual fogging. If the building or room must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pants.

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE SURFACES.

## PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

## DANGER

KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist filtering respirator (NIOSH/MSHA approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

## STATEMENT OF PRACTICAL TREATMENT

### FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor; do not give anything by mouth to an unconscious person.

HOT LINE NUMBERS: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 658-7378.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measure against circulatory shock, respiratory depression and convulsion may be needed.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Net Contents: \_\_\_\_\_ U.S. Gallons Batch No.: 149

## SANITIZING USING A THERMAL FOGGER:

Fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Close room off so fog is confined to room to be treated. Mix one (1) part SYNERGIZE to five (5) parts water. One (1) gallon of SYNERGIZE to four (5) gallons of water. Insert the nozzle of the fogger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute to reach 4,000 cubic feet of space in the room with the thermal fogger. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment. (less time if area is well ventilated).

**\*NOTE:** The fog generated by this method is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone until the fog has completely settled, normally 1-4 hours after fogging. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long shirt sleeves and pants.

07-28-05

09

## TEST CONDITIONS

**Challenge virus:**

Porcine circovirus type 2, American BioResearch Laboratories

**Host:**

PT-1 cells, American BioResearch Laboratories

**Active ingredient in test product:**

Glutaraldehyde, ADBAC

**Neutralizer used:**

Fetal bovine serum (FBS) containing 0.3% glycine

**Dilution:**

1:256 (1 mL test agent + 255 mL diluent)

**Diluent:**

1000 ppm  $\pm$  2.9% AOAC hard water

**Contact time(s):**

10 minutes

**Contact temperature:**

23C

**Organic load:**

$\geq$  5% serum

**Media and reagents:**

RPMI 1640 containing 5% FBS

FBS containing 0.3% glycine

Phosphate Buffered Saline

Tissue culture grade alcohol

Anti-PCV conjugate

1000 ppm  $\pm$  2.9% AOAC hard water

Date Issued: 06/22/06 Project Sheet No. 1 Page No. 1 Laboratory Project Identification No. 366-107			
<b>STUDY TITLE:</b> Virucidal Effectiveness Test Post weaning multisystemic wasting syndrome (Porcine circovirus type 2)		<b>STUDY DIRECTOR:</b> Lauren A. Blaszk	
		Signature: <u>Lauren A. Blaszk</u> Date: <u>6/22/06</u>	
<b>TEST MATERIAL(S):</b> Synergize	<b>LOT NO.</b> 33458 33519	<b>DATE RECEIVED:</b> 06/22/06 06/22/06	<b>DS NO.</b> 8292 8293
<b>PERFORMING DEPARTMENT(S):</b> Virology Department		<b>STORAGE CONDITIONS:</b> Location: E4 <input checked="" type="checkbox"/> Dark <input checked="" type="checkbox"/> Ambient Room Temperature <input type="checkbox"/> Desiccator <input type="checkbox"/> Freezer <input type="checkbox"/> Refrigerator <input type="checkbox"/> Other:	
<b>PROTECTIVE PRECAUTION REQUIRED:</b> MSDS <input checked="" type="checkbox"/> Yes / <input type="checkbox"/> No			
<b>PHYSICAL DESCRIPTION:</b> <input type="checkbox"/> Solid <input checked="" type="checkbox"/> Liquid <input type="checkbox"/> Aerosol <input type="checkbox"/> Other:			
<b>PURPOSE:</b> See attached protocol. <b>AUTHORIZATION:</b> See client signature.			
<b>PROPOSED EXPERIMENTAL START DATE:</b> 06/23/06 <b>TERMINATION DATE:</b> 07/03/06			
<b>CONDUCT OF STUDY:</b> <input type="checkbox"/> FDA <input checked="" type="checkbox"/> EPA <input type="checkbox"/> R&D <input checked="" type="checkbox"/> GLP <input type="checkbox"/> GCP <input type="checkbox"/> Other:			
<b>SPONSOR:</b> Preserve International P.O. Box 17003 Reno, NV 89511		<b>CONTACT PERSON:</b> Gary E. Gaumer Telephone No. (775) 853-9776 FAX No. (775) 853-9212	
<b>TEST CONDITIONS:</b>			
<b>Challenge Organism:</b> <u>Porcine circovirus type 2</u> , American BioResearch Laboratories			
<b>Host Cell Line:</b> PT-1 cells, American BioResearch Laboratories			
<b>Organic Load:</b> <u>≥ 5% serum</u>			
<b>Cell Culture Medium:</b> RPMI 1640 + 5% Fetal bovine serum (FBS)			
<b>Active ingredient(s):</b> Glutaraldehyde, ADBAC			
<b>Neutralizer(s):</b> Fetal bovine serum + 0.3% glycine			
<b>Contact Time(s):</b> 10 minutes <b>Contact Temperature(s):</b> Ambient temperature			
<b>Diluent:</b> <u>1000 ppm± 2.9% AOAC hard water</u>			
<b>Dilution:</b> <u>1:256 (1 mL test agent + 255 mL diluent)</u>			
<b>Incubation Time(s):</b> 5-7 days <b>Incubation Temperature(s):</b> 36±2C in 5±1% CO <sub>2</sub>			



✓ **World Headquarters** P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607  
**Tennessee Operation** 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446  
**California Operation** 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

April 18, 2012

Ms. Velma Noble  
Office of Pesticides Programs (7504C)  
United States Environmental Protection Agency (NOTIFY)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Dear Ms. Noble:

Preserve International hereby submits this notification for Alternate Brand Name for Synergize, EPA registration number 66171-7.

Alternate Brand Name requested: Synergize Cool

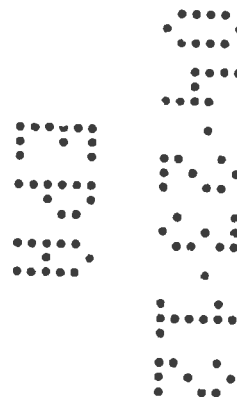
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,  
Preserve International

  
Gary E. Gaumer  
President







United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 66171-7	2. EPA Product Manager Velma Noble	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) SYNERGIZE	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Preserve International PO Box 17003 Reno, NV 89511  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____  Product Name _____	

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated 2/16/12
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 275,250,55,30,4x1,2.5x2		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Gary E. Gaumer		Title President		Telephone No. (Include Area Code) 775-853-9776	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					b. Date Application Received (Stamped)  
2. Signature 		3. Title President			
4. Typed Name Gary E. Gaumer		5. Date February 29, 2012			

## DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO<sub>3</sub>) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

## DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

## USE DIRECTIONS:

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to precleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

**BOOT/SHOE WASH:** To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution must be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

**VEHICLES:** To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

## DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARN, RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.

Manufactured by:

**PRESERVE**  
INTERNATIONAL  
Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com  
Page 1 of 2

# SYNERGIZE

## CLEANER-DISINFECTANT

STAPHYLOCIDAL • PSEUDOMONACIDAL

• SALMONELLACIDAL • VIRUCIDAL\*

• PARVOCIDAL • FUNGICIDAL

ASPERGILLOCIDAL

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, Veterinary Practice, Animal Care, and Animal Laboratory.

## Active Ingredients:

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride.....	26.00%
Glutaraldehyde.....	7.00%
Inert Ingredients.....	67.00%
TOTAL.....	100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

### SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

## DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

EPA Reg. No. 66171-7  
EPA Est. 66171-TN-001, 66171-CA-001  
Patent Number: 5,891,922

Batch No: \_\_\_\_\_ Net Contents: \_\_\_\_\_

## STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

### PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. (For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in pesticide disposal section. Drain for 10 seconds after the flow begins to drip. This procedure two more times.

**General:** Consult Federal, State or local disposal authorities for approved alternative procedures.

## PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

### DANGER

**KEEP OUT OF REACH OF CHILDREN.** Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS:** This product is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

## FIRST AID

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

**HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

# SYNERGIZE

## HATCHERY ROOMS, INCUBATORS, AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING:

All surfaces must be cleaned and disinfected prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices. Fogging is not used as a sanitizing treatment. Close room off so fog is confined to room to be treated. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus.

### A) HATCHERY ROOMS:

Remove all animals and feed from premises, vehicles and enclosures. Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 Fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in be room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.

### B) INCUBATORS AND HATCHERS:

Only for treatment of setters and hatchers after poultry / chicks / eggs have been removed. Not for treatment of hatchers which contain chicks / eggs. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water. Fog three (3) ounces per 100 cubic feet of this fogging solution into setters and hatchers immediately after transfer. Repeat daily. Discontinue Hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 solution of SYNERGIZE. If this is done, fog for 30-90 seconds once per hour or once every two hours.

### C) POULTRY HOUSES AND LIVESTOCK BUILDINGS:

After the house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, ratite facilities, calf pens and vehicles, double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as possible. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. The Fogger itself may be placed just inside the door of the building to be treated, or the nozzle of the fogger may be inserted through a suitable opening in the door or building. The opening must be large enough to accommodate the fog. After fogging, the building must be kept closed for twenty-four (24) hours. After twenty-four (24) hours, the fog must have settled and the house can now be opened and aired. The house must be opened for a minimum of twenty-four (24) hours before it is repopulated with poultry or livestock.

**NOTE:** The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances must a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSH, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they must be washed with detergent and water before use for poultry or livestock.

## AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:

This product may only be used in industrial air washers and air washer systems which have mist-eliminating components.

SYNERGIZE must be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as a basin area. Addition may be made intermittently (Slug Dose) or continuously. Badly fouled systems can be shock treated with SYNERGIZE. Under these conditions, blowdown must be discontinued for up to 24 hours.

SYNERGIZE can be used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

### Intermittent (Slug Dose) Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

### Continuous Feed Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

**VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/ANIMAL LABORATORY/ANIMAL LIFE SCIENCE LABORATORY/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOOS/PET SHOP/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREEDING FACILITIES/BREEDING AND GROOMING ESTABLISHMENT/TACK SHOPS DISINFECTION DIRECTIONS:** For cleaning and disinfecting the following hard, non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, stalls and catteries. Remove all animals (and) feeds from areas to be treated, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers, and other equipment which dispenses for water with soap or detergent, and rinse with potable water before reuse. At 1/2 ounce per gallon of water, in the presence of 1000 ppm of hardness and 5% organic load for a 10-minute contact time, Synergize was found to be effective against Canine Parvovirus.

Staphylococcus aureus A.T.C.C. 6538  
Pseudomonas aeruginosa A.T.C.C. 15442  
Salmonella enterica A.T.C.C. 10708  
Aspergillus fumigatus A.T.C.C. 36267  
Porcine Respiratory & Reproductive Syndrome Virus (PRRS)\*  
Avian Influenza (H5N2)\*  
Escherichia Coli F+  
Porcine circovirus Type 2\*  
Canine parvovirus A.T.C.C. VR-2016\*

Salmonella Choleraesuis  
Salmonella Enteritidis



## DOT SHIPPING NAME

UN3264, Corrosive Liquid, Acidic, Inorganic,  
n.o.s. (Phosphoric Acid), 8, PG III

2/29/2012





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Gary E. Gaumer  
 Preserve International  
 P.O. Box 17003  
 Reno, NV 89511

FEB 16 2012

SUBJECT: Synergize  
 EPA Registration Number: 66171-7  
 Application Date: August 31, 2011  
 Receipt Date: September 7, 2011

Dear Mr. Gaumer:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(C)(7)(A) is acceptable with the condition below.

- On page 2 of the proposed label in the section B) INCUBATORS AND HATCHERS, the statement "disperse the sanitizing solution as a fog" must be revised as the fogging use is only an adjunct treatment (Agency letters of 12/30/2010 and 7/23/2010). Revise this statement to read "...disperse the solution as a fog..." by deleting the word "sanitizing".

#### Efficacy Data

The following study has been reviewed in support of this product. The review of this data is attached.

Data Requirement	Means of Support	Status
Salmonella enteric subsp. enterica serovar enteritidis (ATCC 13076)	Submitted study, MRID 485944-01	Acceptable, 1/2 ounce product per 1 gallon of water, 5% soil, contact time of 10 minutes

#### General Comments

A stamped copy of the accepted labeling with conditions is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6 (e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. Should you have any questions concerning this letter, please contact Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,

A handwritten signature in black ink, appearing to read 'Velma Noble', is written over the printed name.

Velma Noble  
Product Manager (31)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Attachments: Stamped label and Efficacy review DP Barcode: D394286

# Material Sent for Data Extraction

Reg # 66 111-7

Description: Notification

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated \_\_\_\_\_

☒ Notification Dated 11/15/11

☐ New CSF(s) Dated \_\_\_\_\_

☐ Other: \_\_\_\_\_

☒ Decision #: 456778, 454407

☐ Other Action/Comments: \_\_\_\_\_

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Tracy Lantz, Emilia Orquendo

Phone: 703 308 6415 Division: AD  
347 0199

Date: 12/2/11



**Reg. Number 66171-7**  
Emilia Oiguenblik to: gegaumer  
Cc: Tracy Lantz

12/02/2011 04:18 PM

From: Emilia Oiguenblik/DC/USEPA/US  
To: gegaumer@preserveinc.com  
Cc: Tracy Lantz/DC/USEPA/US@EPA

Dear Mr. Gaumer:

Please read an attached efficacy review for Reg. # 66171-7 , fix the label and e-mail it to me.

Please remove these organisms from the label:

Salmonella Dublin  
Salmonella Heidelberg  
Salmonella paratyphi  
Salmonella typhi  
Salmonella typhimurium  
Salmonella pullorum  
Salmonella Gallinarum  
Salmonella Branderburg

We can not approve your amendment until these organisms have been removed from the label.

Thank you for your assistance,

Emilia Oiguenblik  
PYS-8824  
703-347-0199

1 attachment



[Untitled].pdf



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY  
AND POLLUTION  
PREVENTION

November 7, 2011

**MEMORANDUM**

SUBJECT: Efficacy Review for Synergize;  
EPA File Symbol 66171-7;  
DP Barcode: D394286

FROM: Karen Hill, Ph.D.  
Microbiologist  
Product Science Branch  
Antimicrobials Division (7510P)

THRU: Tajah Blackburn, Ph.D.  
Team Leader  
Product Science Branch  
Antimicrobials Division (7510P)

TO: Velma Noble RM31/ Tracy Lantz  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

APPLICANT: Preserve International  
P.O. Box 17003  
Reno, NV 89511

**FORMULATION FROM THE LABEL:**

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Alkyl (C <sub>12</sub> 67%, C <sub>14</sub> 25%, C <sub>16</sub> 7%, C <sub>18</sub> 1%) dimethyl benzyl ammonium chloride .....	26.00%
Glutaraldehyde.....	7.00%
<u>Inert Ingredients</u> .....	<u>67.00%</u>
Total.....	100.00%

## **I BACKGROUND**

The product, Synergize, is a registered product (EPA Registration No. 66171-7). The applicant has requested to amend the registration to include disinfectant claims against *Salmonella enterica subsp. enterica serovar enteritidis* on hard non-porous surfaces for industrial and animal care and processing facilities. The product is specifically intended for industrial use in the following Animal and Poultry Housing Facilities: Hatcheries and Swine Producing Facilities, Turkey Breeder, Fryer, Grow Out, and Layer. It is also intended for use on the following equipment: Feeders, Farrowing Barns, Nurseries, Creep Areas, Hauling Equipment, Dressing Plants, Blocks, Loading Equipment, Chutes, and Waterers. The label claims that the product is effective in hard water (as much as 1000 ppm  $\text{CaCO}_3$ ) and in the presence of 5% serum. The study was performed at Antimicrobial Test Laboratories 3000 Joe DiMaggio Blvd. Suite #32 Round Rock, Texas 78665.

The data package included a letter from the applicant dated August 31, 2011, the Data Matrix, the proposed label, one efficacy study (MRID No. 485944-01), Statement of No Confidentiality Claims, Good Laboratory Practice Compliance statement, and Quality Assurance statement for referenced study.

## **II USE DIRECTIONS**

The product is designed to clean and disinfectant hard non-porous surfaces. The product may be used to treat hard non-porous surfaces including: glass, garbage cans, walls, floors, telephone booths, tables, sinks, and refrigerator exteriors. The proposed label claims it may be used on stainless steel, glass, hard non-porous treated wood, polyvinyl chloride, polypropylene, acrylic, ethylene propylene, tin, vinyl, viton, sealed fiberglass, nitrile, polyurethane, galvanized metal, brass, zinc, tin, glazed ceramic and tile, chrome, and aluminum. Directions on the proposed label provided the following instructions for the use and preparation of the product as a disinfectant:

Apply ½ ounce SYNERGIZE per gallon of water (1:256 dilution). Apply with cloth, sponge, mop, or mechanical coarse spray device, allow surfaces to remain wet for 10 minutes, rinse surfaces with clean water, and allow surfaces to dry.

## **III AGENCY STANDARDS**

### Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Bacteria; Additional Bacteria):

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against specific bacteria with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific bacteria on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least  $10^4$  microorganisms survived the carrier-drying step.

#### IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 485944-01 "AOAC Use – Dilution Test Method," Test Organism: *Salmonella enterica subsp. enterica serovar enteritidis* (ATCC 13076), for Synergize, by Jason Williams. Study conducted at Antimicrobial Test Laboratories. Study completion date- August 2, 2011. Study Identification No. is GLP1077.

This study was conducted against *Salmonella enterica subsp. enterica serovar enteritidis* (ATCC 13076). Two lots (Lots No. 37817 and 37818) of the product Synergize were tested using the provided Antimicrobial Test Laboratories Protocol No. P1084. The product was diluted as 1 part test substance and 255 parts diluent (1:256 dilution). The product was diluted in 1010ppm AOAC hard water. The test culture was incubated for 48±2 hours (48 hrs. and 28 min. indicated in final report) at 36±1°C. Equine serum was added to the test culture to achieve 5% serum load. The stainless steel penicylinder carriers were submerged in 48±2 hours old suspension of test organism for 15 minutes at room temperature. Following, the carriers were placed on double filter paper-lined Petri dishes and allowed to dry for 38 minutes at 35.4°C. The inoculated carriers were each submerged in 10ml of test substance for 10 minutes at 22.2°C. Afterwards, the carriers were transferred to 10mL of AOAC Modified Lethen Broth. All subcultures were incubated for 48±2 hours at 36±1°C prior to examination of the subcultures for the presence or absence of visible growth. Controls for both product lots included carrier count, sterility, viability, and neutralization confirmation.

#### V RESULTS

Lot No.	Microorganism	Number of Positive Carriers / Number of Carriers	Average CFU/Carrier
37817	<i>Salmonella enterica</i> (ATCC 13076)	0/10	9.03 X 10 <sup>5</sup>
37818	<i>Salmonella enterica</i> (ATCC 13076)	0/10	9.03 X 10 <sup>5</sup>

#### VI CONCLUSIONS

1. The submitted efficacy data support the use of the product, Synergize, as a disinfectant with bactericidal activity against the following microorganism on hard, non-porous surfaces in the presence of a 5% organic soil load and 1000ppm hard water for a 10-minute contact time:

*Salmonella enterica subsp. enterica serovar enteritidis* (ATCC 13076) MRID 485944-01

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.



## VI RECOMMENDATIONS

1. The proposed label claims that the product, Synergize, is an effective disinfectant against the following microorganisms on hard, non-porous surfaces in the presence of 5% organic serum and hard water for a 10 minute contact time:

*Salmonella enterica subsp. enterica serovar Enteritidis*

These claims are acceptable as they are supported by the submitted data.

### Label:

- Please remove claims for the following organisms in the absence of acceptable efficacy data:

Salmonella Dublin  
Salmonella Heidelberg  
*Salmonella paratyphi*  
*Salmonella typhi*  
*Salmonella typhimurium*  
*Salmonella pullorum*  
Salmonella Gallinarum  
Salmonella Brandenburg

The ATCC numbers for *Salmonella enterica subsp. enterica serovar enteritidis* and *E. coli* F18 are required on master label or data matrix.

- On page 2 of the proposed label in Section B) Incubators and Hatchers, the statement "disperse the sanitizing solution as a fog" conflicts with earlier language regarding the use as a disinfectant.

#### DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO<sub>3</sub>) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, sealed fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

#### DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

#### THE DIRECTIONS:

disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator interiors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to pre-cleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

**BOOT/SOUE WASH:** To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution must be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

**VEHICLES:** To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

#### DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.
- 7) Immerse equipment used in handling and restraining animals, forks, shovels, and spears used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.
- 8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARNs, RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.

Manufactured by:  
**PRESERVE**  
INTERNATIONAL

Reno, NV 89511 • (800) 995-1607 • [www.preserveinternational.com](http://www.preserveinternational.com)

Page 1 of 2

# SYNERGIZE

## CLEANER-DISINFECTANT

STAPHYLOCIDAL • PSEUDOMONACIDAL

• SALMONELLACIDAL • VIRUCIDAL\*

• PARVOCIDAL • FUNGICIDAL

ASPERGILLOCIDAL

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, Veterinary Practice, Animal Care, and Animal Laboratory.

#### Active Ingredients:

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride.....	26.00%
Glutaraldehyde.....	7.00%
Inert Ingredients.....	67.00%
TOTAL.....	100.00%

## KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set, or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

#### DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

EPA Reg. No.  
EPA Est.  
Patent Number:

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

66171-7  
66171-TN-001, 66171-CA-001  
5,891,922

Batch No: \_\_\_\_\_ Net Contents: \_\_\_\_\_

FEB 16 2012

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.

66171-7

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

#### PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

#### PESTICIDE DISPOSAL:

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**Container Handling:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

**General:** Consult Federal, State or local disposal authorities for approved alternative procedures.

#### PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

#### DANGER

**KEEP OUT OF REACH OF CHILDREN.** Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS:** This product is toxic to fish aquatic invertebrates, oysters, and shrimp. Do not apply directly to water. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

#### FIRST AID

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes; remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye; call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing; rinse skin immediately with plenty of water for 15-20 minutes; call a poison control center or doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice; have person sip a glass of water if able to swallow; do not induce vomiting unless told to do so by the poison control center or doctor; do not give anything by mouth to an unconscious person.

**HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1 (800) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

# SYNERGIZE

## HATCHERY ROOMS, INCUBATORS, AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING:

All surfaces must be cleaned and disinfected prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices. Fogging is not used as a sanitizing treatment. Close room off so fog is confined to room to be treated. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus.

### A) HATCHERY ROOMS:

Remove all animals and feed from premises, vehicles and enclosures. Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 Fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in be room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.

### B) INCUBATORS AND HATCHERS:

Only for treatment of setters and hatchers after poultry / chicks / eggs have been removed. Not for treatment of hatchers which contain chicks / eggs. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water. Fog three (3) ounces per 100 cubic feet of this fogging solution into setters and hatchers immediately after transfer. Repeat daily. Discontinue Hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the sanitizing solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 solution of SYNERGIZE. If this is done, fog for 30-90 seconds once per hour or once every two hours.

### C) POULTRY HOUSES AND LIVESTOCK BUILDINGS:

After the house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, ratite facilities, calf pens and vehicles, double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as possible. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. The Fogger itself may be placed just inside the door of the building to be treated, or the nozzle of the fogger may be inserted through a suitable opening in the door or building. The opening must be large enough to accommodate the nozzle. After fogging, the building must be kept closed for twenty-four (24) hours. After twenty-four (24) hours, the fog must have settled and the house can now be opened and aired. The house must be opened for a minimum of twenty-four (24) hours before it is repopulated with poultry or livestock.

**NOTE:** The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances must a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSH, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they must be washed with detergent and water before use for poultry or livestock.

## AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:

This product may only be used in industrial air washers and air washer systems which have mist-eliminating components.

SYNERGIZE must be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as a basin area. Addition may be made intermittently (Slug Dose) or continuously. Badly fouled systems can be shock treated with SYNERGIZE. Under these conditions, blowdown must be discontinued for up to 24 hours.

SYNERGIZE can be used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

### Intermittent (Slug Dose) Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

### Continuous Feed Method:

**Initial Dose:** When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

**Subsequent Dose:** When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

**VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/ANIMAL LABORATORY/ANIMAL LIFE SCIENCE LABORATORY/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOOS/PET SHOP/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREEDING FACILITIES/BREEDING AND GROOMING ESTABLISHMENT/TACK SHOPS DISINFECTION DIRECTIONS:** For cleaning and disinfecting the following hard, non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, stalls and catteries. Remove all animals (and) feeds from areas to be treated, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used for removing litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, automatic feeders, waterers, and other equipment which dispenses food or water with soap or detergent, and rinse with potable water before reuse. At 1/4 ounce per gallon of water, in the presence of 1000 ppm of hardness and 5% organic load for a 10-minute contact time, this product was found to be effective against Canine Parvovirus.

Staphylococcus aureus A.T.C.C. 6538

Salmonella Choleraesuis

Pseudomonas aeruginosa A.T.C.C. 15442

Salmonella Enteritidis

Salmonella enterica A.T.C.C. 10708

Aspergillus fumigatus A.T.C.C. 36607

Porcine Respiratory & Reproductive Syndrome Virus (PRRS)\*

Avian Influenza (H3N2)\*

Escherichia Coli F18

Porcine circovirus Type 2\*

Canine parvovirus A.T.C.C. VR-2016\*

Manufactured by:  
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Page 2 of 2

## DOT SHIPPING NAME

UN3264, Corrosive Liquid, Acidic, Inorganic,  
n.o.s. (Phosphoric Acid), 8, PG III

12/7/11

# DATA PACKAGE BEAN SHEET

Date: 21-Sep-2011

Page 1 of 2

Decision #: 454407

DP #: (394286)

PRIA

Parent DP #:

Submission #: 902892

E-Sub #:

## \*\*\* Registration Information \*\*\*

### Registration: 66171-7 - SYNERGIZE

Company: 66171 - PRESERVE INTERNATIONAL

Risk Manager: RM 31 - Velma Noble - (703) 308-6233 Room# PY1 S-8855

Risk Manager Reviewer: Tracy Lantz TLANTZ

Sent Date: \_\_\_\_\_

Calculated Due Date: 28-Jan-2012

Edited Due Date: \_\_\_\_\_

Type of Registration: Product Registration - Section 3

Action Desc: (A570) AMENDMENT;NON-FAST TRACK;

Ingredients: 043901, Glutaraldehyde(7%)

069175, Alkyl\* dimethyl benzyl ammonium chloride \*(67%C12, 25%C14, 7%C16, 1%C18)(26%)

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: 21-Sep-2011

Due Back: \_\_\_\_\_

DP Ingredient: 043901, Glutaraldehyde

069175, Alkyl\* dimethyl benzyl ammonium chloride \*(67%C12, 25%C14, 7%C16, 1%C18)

DP Title: \_\_\_\_\_

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: \_\_\_\_\_

### Assigned To

Date In

Date Out

Organization: AD / PSB

9/21/11

Last Possible Science Due Date: 29-Dec-2011

Team Name: EET

9/21/11

Science Due Date: 12/6/11

Reviewer Name: Karen Hill

10/25/11

Sub Data Package Due Date: 12/20/11

Contractor Name: \_\_\_\_\_

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

Tajah:L Please review submitted efficacy study. MRID 48594491. Label, cover letter and data matarix included. Thanks

RECEIVED  
9/21/11

48594401

Williams, J. (2011) AOAC Use-Dilution Test Method: Synergize: *Salmonella enterica* Subsp. *enterica* serovar Enteritidis. Project Number: GLP1077, P1084. Unpublished study prepared by Antimicrobial Test Laboratories. 24p.

810.2100/Products for use on hard surfaces-basic efficacy data requirements



**Re: Reg. Number 66171-7**  
Gary E. Gaumer to: Emilia Oiguenblik  
Cc: Tracy Lantz

12/07/2011 01:58 PM

1 attachment



Synergize 12-7-11.pdf

Hello Emilia,

Thank you for your note.

Per your request, we have removed the organisms from the Synergize label.  
Please use the attached label.

Thank you for your time and help,

GG

On Dec 2, 2011, at 1:18 PM, Oiguenblik.Emilia@epamail.epa.gov wrote:

>  
> Dear Mr. Gaumer:  
>  
> Please read an attached efficacy review for Reg. # 66171-7 , fix the  
> label and e-mail it to me.  
>  
> Please remove these organisms from the label:  
>  
> Salmonella Dublin  
> Salmonella Heidelberg  
> Salmonella paratyphi  
> Salmonella typhi  
> Salmonella typhimurium  
> Salmonella pullorum  
> Salmonella Gallinarum  
> Salmonella Branderburg  
>  
> We can not approve your amendment until these organisms have been  
> removed from the label.  
>  
>  
> Thank you for your assistance,  
>  
>  
> Emilia Oiguenblik  
> PYS-8824  
> 703-347-0199  
>  
>  
>  
>  
> <[Untitled].pdf>



# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 9-7-11

Experts In-Processing Signature: MF Harrington Date 9-9-11 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>66171-7</u>		EPA Receipt Date: <u>9-7-11</u>				
Items for Review				Yes	No	N/A*
1	<b>Application Form</b> (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)					X
	a) All inerts (link to <a href="http://www.epa.gov/opprd001/inerts/">http://www.epa.gov/opprd001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	<b>Data Matrix</b> (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	<b>5 Copies of Label</b> (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )			X
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			



**Comments:**

Passed 865 Review (MRID 485944) with no  
need to contact the registrant

TD 9/12/11

\* N/A – Not Applicable

**Footnotes**

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/oppbppd1/biopesticides/contacts\\_bppd.html](http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.html)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

September 8, 2011

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-454407  
EPA File Symbol or Registration Number: 66171-7  
Product Name: SYNERGIZE  
EPA Receipt Date: 07-Sep-2011  
EPA Company Number: 66171  
Company Name: PRESERVE INTERNATIONAL

GARY GAUMER  
PRESERVE INTERNATIONAL  
PO Box 17003  
RENO, NV 89511-

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A570

AMENDMENT;NON-FAST TRACK;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,

A handwritten signature in black ink, appearing to be "M. J. [unclear]", is written over the word "Sincerely,".

Front End Processing Staff  
Information Technology & Resources Management Division

**Fee for Service**

W  
{902892<~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies?      ☐ Fee Waiver?

☐ volpay    % Reduction: \_\_\_\_\_

for Division

- ☒ AD
- ☐ BPPD
- ☐ RD

Risk Mgr.      **31**

Receipt No.

S- **902892**

EPA File Symbol/Reg. No.

**66171-7**

Pin-Punch Date:

**9/7/2011**

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ **3,474<sup>00</sup>**

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Team 3

Date: 09/08/2011

Remarks:

**Online Payment****Step 3: Confirm Payment****1 | 2 | 3****Thank you.****Your transaction has been successfully completed.****Pay.gov Tracking Information****Application Name:** PRIA Service Fees**Pay.gov Tracking ID:** 254CRQEK**Agency Tracking ID:** 74235898871**Transaction Date and Time:** 09/08/2011 14:03 EDT**Payment Summary**

Address Information	Account Information	Payment Information
<b>Account Holder Name:</b> Gary Gaumer	<b>Card Type:</b> American Express	<b>Payment Amount:</b> \$869.00
<b>Billing Address:</b> PO Box 3135	<b>Card Number:</b> *****2007	<b>Transaction Date and Time:</b> 09/08/2011 14:03 EDT
<b>Billing Address 2:</b>	<b>Decision Number:</b>	
<b>City:</b>	<b>Registration Number:</b> 66171-7	
<b>State / Province:</b>	<b>Company Name:</b> Preserve International	
<b>Zip / Postal Code:</b>	<b>Company Number:</b> 66171	
<b>Country:</b> USA	<b>Action Code:</b> A570	

# Receipt for Section 3

S: 902692

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☒ Yes ☐ No

Application Type: Amendment

Billable: ☒ Yes ☐ No

Company: 68171 PRESERVE INTERNATIONAL V

Risk Manager: Antimicrobials Division, Risk Management Team 31

Product #: 68171-7 Product Name: SYNERGIZE

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 31-Aug-2011

OPP Rec'd Date: 07-Sep-2011

Front End Date: 08-Sep-2011

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Label amendment

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

Paper Label

View/Edit





✓ **World Headquarters** P.O. Box 17003, Reno, NV 89511 • Bus: (775) 853-9776 • Fax: (775) 406-3413 • USA: (800) 995-1607  
**Tennessee Operation** 1213 Empire Avenue, Memphis, TN 38107 • Bus: (901) 272-0031 • Fax: (901) 726-6446  
**California Operation** 1355 Paulson Road, Turlock, CA 95380 • Bus: (209) 664-1607 • Fax: (209) 664-1728

August 31, 2011

Ms. Velma Noble  
Office of Pesticides Programs (7504C)  
United States Environmental Protection Agency (AMEND)  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Dear Ms. Noble:

Preserve International is submitting amendment documents, for our product Synergize, EPA Registration Number 66171-7:

1 Addition of the following Salmonella enterica serotypes:

Salmonella Enteritidis  
Salmonella Choleraesuis  
Salmonella Dublin  
Salmonella Heidelberg  
Salmonella Paratyphi  
Salmonella Typhi  
Salmonella Typhimurium  
Salmonella Pullorum  
Salmonella Gallinarum  
Salmonella Brandenburg

We have included the required: 1) USEPA Form 8570-1, Application for Pesticide, 2) Formulator's Exemption for both active ingredients, 3) Certification with respect to citation of data, 4) Data matrix, 5) six copies of the proposed labeling and 6) three copies of the confirmatory data.

If I may be of further assistance, please feel free to contact me at 775-853-9776.

Thank you for your time and consideration.

Sincerely,  
Preserve International



Gary E. Gaumer  
President



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number  
 Preserve International, PO Box 17003, Reno, NV 89511

EPA Registration Number/File Symbol  
 66171-7

Active Ingredient(s) and/or representative test compound(s)

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride, Glutaraldehyde

Date

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)

Farm, Indoor Non-Food, Animal, Cooling and Processed Water

Product Name

Synergize

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).



I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)



I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]



I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

Typed or Printed Name and Title

Gary E. Gaumer, President



United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address

Preserve International

PO Box 17003

Reno, NV 89511

EPA File Symbol/Registration Number

66171-7

Product Name

Synergize

Date of Confidential Statement of Formula (EPA Form 8570-4)

9/11/03

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride  
Glutaraldehyde

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

## Source

Active Ingredient	Product Name	Registration Number
Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride		
Glutaraldehyde		
Signature	Name and Title Gary E. Gaumer, President	Date 8/24/11

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
Copy 2 - Applicant copy

\*Product ingredient source information may be entitled to confidential treatment\*



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.  
WASHINGTON, D.C. 20460

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## DATA MATRIX

Date May 24, 2011

EPA Reg No./File Symbol 66171-7

Page 1 of 3

Applicant's/Registrant's Name &amp; Address

Product

Preserve International, PO Box 17003, Reno, NV 89511

Synergize

Ingredient Alkyl dimethyl benzyl ammonium chloride, Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Submission of Product Chemistry and Efficacy Data	44433700	Preserve International	Own	
	in support of the application for registration of Synergize				
	Disinfectant.				
61-1	Product Identity & Disclosure of Ingredients	44433701	Preserve International	Own	
61-2	Product Identity - Beginning Materials & Mfg. Process	44433701	Preserve International	Own	
61-3	Product Identity - Discussion of Formation of Impurities	44433701	Preserve International	Own	
62-2	Analysis of Ingredients - Certification of Limits	44433701	Preserve International	Own	
63-0	Reports of Multiple Physical/Chemical Characteristics	44433701	Preserve International	Own	
63-0	Selected Physical Characteristics	44433702	Preserve International	Own	
62-1	Analysis of Ingredients-Preliminary Analysis of Product	44433703	Preserve International	Own	
62-3	Analysis of Ingredients-Analytical Method to Verify Limits	44433703	Preserve International	Own	
62-1	Analysis of Ingredients-Preliminary Analysis of Product	44433704	Preserve International	Own	
62-3	Analysis of Ingredients-Analytical Method to Verify Limits	44433704	Preserve International	Own	
	AOAC Disinfectant Testing (Efficacy)	44433705	Preserve international	Own	
	AOAC Disinfectant Testing (Efficacy)-Addendum 1		Preserve International	Own	

Signature

Name and Title

Gary E. Gaumer, President

Date

8/29/11



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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## DATA MATRIX

Date May 24, 2011

EPA Reg No./File Symbol 66171-7

Page 2 of 3

Applicant's/Registrant's Name &amp; Address

3

Product

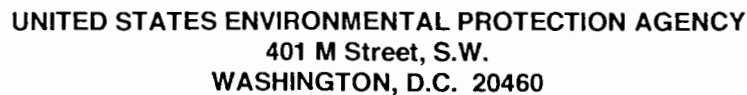
Synergize

Ingredient Alkyl dimethyl benzyl ammonium chloride, Glutaraldehyde

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Toxicity Data Submission Cover Sheet	44569500	Preserve International	Own	
81-1	Acute Tox & Irritation - Acute Oral Toxicity	44569501	Preserve International	Own	
81-2	Acute Tox & Irritation - Acute Dermal Toxicity	44569502	Preserve International	Own	
81-5	Acute Tox & Irritation - Primary Dermal Irritation	44569503	Preserve International	Own	
81-4	Acute Tox & Irritation - Primary Eye Irritation	44569504	Preserve International	Own	
81-3	Acute Tox & Irritation - Acute Inhalation Toxicity	44569505	Preserve International	Own	
81-6	Acute Tox & Irritation - Dermal Sensitization	44569506	Preserve International	Own	
	Fungicidal Data Submission Cover Sheet	45147100	Preserve International	Own	
	AOAC Fungicidal Product Test - Efficacy Data	45147101	Preserve International	Own	
	Porcine Respiratory & Reproductive Cover Sheet	46391300	Preserve International	Own	
	Porcine Respiratory & Reproductive Syndrome Virus Data	46391301	Preserve International	Own	
	Avian Influenza A (H3N2) Virus Cover Sheet	46770300	Preserve International	Own	
	Avian Influenza A (H3N2) Virus Data	46770301	Preserve International	Own	
	Escherichia coli (F18) Cover Sheet	46770300	Preserve International	Own	
	Escherichia coli (F18) Data	46770302	Preserve International	Own	
Signature				Name and Title	Date
				Gary E. Gaumer, President	8/24/11

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



Form Approved OMB No. 2070-0060

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## DATA MATRIX

Date May 24, 2011

EPA Reg No./File Symbol 66171-7

Page 3 of 3

**licant's/Registrant's Name & Address**

Serve International, PO Box 17003, Reno, NV 89511

Product

## Synergize

**Ingredient** Alkyl dimethyl benzyl ammonium chloride, Glutaraldehyde

[illegible]

